Framework for Environmental Health Risk Management

The Presidential/Congressional Commission on Risk Assessment and Risk Management

Final Report
Volume 1
1997

The Presidential/Congressional Commission on Risk Assessment and Risk Management

Staff

Gail Charnley, Executive Director

Sharon Newsome, Associate Director

Joanna Foellmer, Program Specialist and Designated Federal Official

Office: 529 14th Street, N.W., Suite 420
Washington, DC 20045
Tel. 202-233-9537
Fax: 202-233-9540
WWW: http://www.riskworld.com

All photos courtesy of Steve Delaney, U.S. EPA, unless otherwise credited.

Preface

In the 1990 Clean Air Act Amendments, Congress mandated that a Commission on Risk Assessment and Risk Management be formed to:

> *...make a full investigation of the policy implications and appropriate uses of risk assessment and risk management in regulatory programs under various Federal laws to prevent cancer and other chronic human health effects which may result from exposure to hazardous substances.*

The Commission was assembled in May 1994. Our members included specialists in public health, occupational and environmental health, medicine, pediatrics, toxicology, epidemiology, engineering, law, and public policy. The members were appointed—six by Congress, three by President Clinton, and one by the president of the National Academy of Sciences—from health and environmental organizations, academia, research institutes, a law firm, and industry. Members also have experience in federal, state, and local governments. We held hearings across the country to obtain input from interested and concerned parties. The information and insights provided by these forums, as well as public comments on our June 1996 Draft Report, provided valuable contributions to our deliberations, findings, and recommendations.

A clear need to modify the traditional approaches used to assess and reduce risks emerged as a major theme from our deliberations. These approaches rely on a chemical-by-chemical, medium-by-medium, risk-by-risk strategy. They tend to focus attention on refining assumption-laden mathematical estimates of the small risks associated with exposures to individual chemicals, rather than on the overall goal of reducing risk and improving health status.

With this volume, which constitutes Volume 1 of our two-volume Final Report, the Commission introduces a unique Risk Management Framework to guide investments of valuable public-sector and private-sector resources in researching, assessing, characterizing, and reducing risk. We set forth principles for making good risk management decisions and for actively engaging stakeholders in the process. Our Framework is intended to catalyze a new generation of risk-based environmental and health protection. Building on current practices, it adds important new dimensions to the risk management process.

The Commission's Framework defines a clear, six-stage process for risk management that can be scaled to the importance of a public health or environmental problem and that:

- Enables risk managers to address multiple relevant contaminants, sources, and pathways of exposure, so that threats to public health and the environment can be evaluated more comprehensively than is possible when only single chemicals in single environmental media are addressed.

- Engages stakeholders as active partners so that different technical perspectives, public values, perceptions, and ethics are considered.

- Allows for incorporation of important new information that may emerge at any stage of the risk management process.

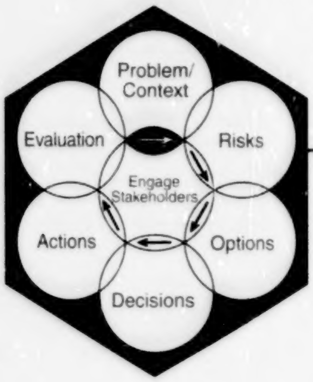
In response to public commenters on our June 1996 Draft Report, we decided to issue a two-volume final report. The first volume focuses solely on our Risk Management Framework and its implementation. This publication has been prepared for regulatory authorities and others who may participate in the risk management process as risk managers or stakeholders. We have provided a glossary for those who seek more information and listed resource documents and organizations at the end of this report. Volume 2, to be published in February 1997, addresses many other issues related to health and environmental risk-based decisions, including recommendations for specific federal regulatory programs and agencies. The table of contents for Volume 2 is provided in an appendix to this report.

The Commission gratefully acknowledges the valuable contributions made by the many people who testified during our deliberations or provided written comments on our Draft Report. We also acknowledge and appreciate the time and effort that regulatory agencies devoted to providing us with needed information and resources. Finally, we acknowledge members and staff of the Congress and leaders and staff of the Clinton Administration for the interest they have taken in our findings and recommendations. We look forward to continuing to work with them to implement the recommendations.

Gilbert S. Omenn
Chair

NOTE: The Commission's June 1996 Draft Report, both volumes of our Final Report, and all supplementary reports (listed in Appendix 6 of Volume 2) can be found on the Commission's homepage at the Riskworld website: http://www.riskworld.com.

Contents
Volume 1



The Commission's Risk Management Framework

What Is Risk Management?

During the last 25 years, our nation has made tremendous progress in improving the quality of our environment and our workplaces, as well as the safety of pharmaceutical drugs, food, and other consumer products. Much of this progress has relied, explicitly or implicitly, on a process called *risk management*.

Risk management is the process of identifying, evaluating, selecting, and implementing actions to reduce risk to human health and to ecosystems. The goal of risk management is scientifically sound, cost-effective, integrated actions that reduce or prevent risks while taking into account social, cultural, ethical, political, and legal considerations.

Our definition of risk management is broader than the traditional definition, which is restricted to the process of evaluating alternative regulatory actions and selecting among them. In recent years, the scope and tools of risk management have broadened considerably beyond regulatory actions taken by federal, state, and local government agencies, for two reasons:

- Government risk managers now often consider both regulatory and voluntary approaches to reducing risk. This is particularly important as our society is challenged to solve more complex risk problems, especially those that cut across environmental media, with limited resources.
- Increasingly, risk management is being conducted outside of government arenas, by individual citizens, local businesses, workers, industries, farmers, and fishers. This decentralization has resulted in part from the growing recognition that decision-making is improved by the involvement of those affected by risk problems ("stakeholders").

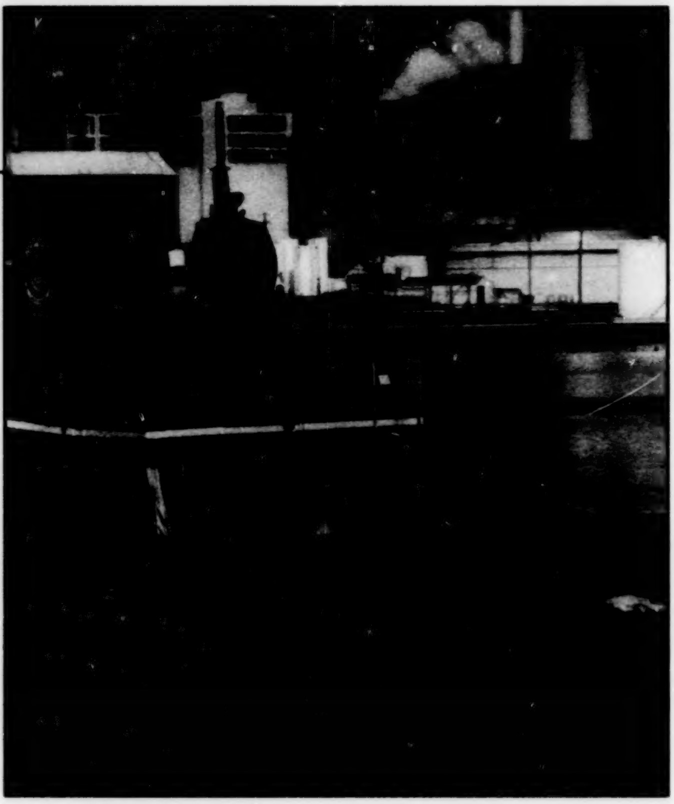
What Is "Risk"?

Risk is defined as the probability that a substance or situation will produce harm under specified conditions. Risk is a combination of two factors:

- The **probability** that an adverse event will occur (such as a specific disease or type of injury).
- The **consequences** of the adverse event.

Risk encompasses impacts on public health and on the environment, and arises from **exposure** and **hazard**. Risk does not exist if exposure to a harmful substance or situation does not or will not occur. Hazard is determined by whether a particular substance or situation has the potential to cause harmful effects.

The Commission's Risk Management Framework



Risks to human health can come from many sources: industrial facilities, combustion engines, and different media—air, water, or soil.

During the traditional risk management process, decision-makers (typically government officials and other risk managers) gather information about a situation that poses or may pose a risk to human health and to ecological health. Air pollution, water pollution, workplace exposures, and the introduction of new pharmaceutical or consumer products are examples of situations that could pose risks to health or the environment. Risk managers use this information they have gathered to consider the:

- Nature and magnitude of risks.
- Need for reducing or eliminating the risks.
- Effectiveness and costs of options for reducing the risks.

In some cases, risk managers also consider the economic, social, cultural, ethical, legal, and political implications associated with implementing each option, as well as any worker health, community health, or ecological hazards the options may cause. In other cases, laws or procedures hinder risk managers from considering those implications and impacts.

The Need for a More Comprehensive Approach to Risk Management: The Commission's Risk Management Framework

In the environmental arena, statutes and legal precedents tend to dictate risk management approaches that focus on one type of risk (e.g., cancers or birth defects in humans) posed by a single chemical in a single medium (air, water, or land). Conclusions about risk are based almost exclusively on observations of toxicity from high doses of the chemical in laboratory animals or in the workplace. While these approaches have contributed to tremendous progress in reducing health, safety, and environmental risks in recent decades, they are not adequate for addressing the more complex risk problems we now face.

Creative, integrated strategies that address multiple environmental media and multiple sources of risk are needed if we are to sustain and strengthen the environmental improvements and risk reduction our nation has attained over the last 25 years. To help meet these needs, the Commission has developed a systematic, comprehensive Risk Management Framework, illustrated and summarized on page 3.

Framework for Risk Management

The Commission's Framework is designed to help all types of risk managers—government officials, private sector businesses, individual members of the public—make good risk management decisions (see "Principles for Risk Management Decision-Making" on page 4). The Framework has six stages:

Define the **problem** and put it in **context**.

Analyze the **risks** associated with the problem in context.

Examine **options** for addressing the risks.

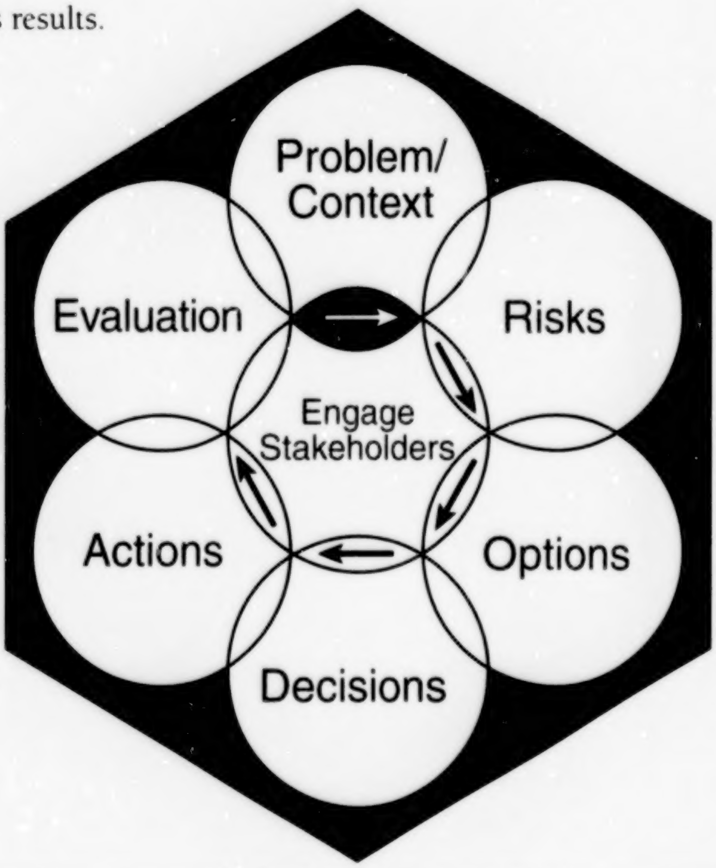
Make **decisions** about which options to implement.

Take **actions** to implement the decisions.

Conduct an **evaluation** of the action's results.

The Framework is conducted:

- In **collaboration** with stakeholders.
- Using **iterations** if new information is developed that changes the need for or nature of risk management.



The Commission's Risk Management Framework

The Framework is general enough to work in a wide variety of situations. The level of effort and resources invested in using the Framework can be scaled to the importance of the problem, potential severity and economic impact of the risk, level of controversy surrounding it, and resource constraints. The Framework is primarily intended for risk decisions related to setting standards, controlling pollution, protecting health, and cleaning up the environment. It is useful for addressing these types of decisions at a local community level (e.g., siting an incinerator or cleaning up a hazardous waste site) or a national level (e.g., developing a national program for controlling motor vehicle emissions). The Framework need not be invoked for risk situations that are routinely and expeditiously managed—for example, by hazardous

Principles for Risk Management Decision-Making

A good risk management decision . . .

- Addresses a clearly articulated problem in its public health and ecological context.
- Emerges from a decision-making process that elicits the views of those affected by the decision, so that differing technical assessments, public values, knowledge, and perceptions are considered.
- Is based on a careful analysis of the weight of scientific evidence that supports conclusions about a problem's potential risks to human health and the environment.
- Is made after examining a range of regulatory and nonregulatory risk management options.
- Reduces or eliminates risks in ways that:
  - Are based on the best available scientific, economic, and other technical information.
  - Account for their multisource, multimedia, multichemical, and multirisk contexts.
  - Are feasible, with benefits reasonably related to their costs.
  - Give priority to preventing risks, not just controlling them.
  - Use alternatives to command-and-control regulation, where applicable.
  - Are sensitive to political, social, legal, and cultural considerations.
  - Include incentives for innovation, evaluation, and research.
- Can be implemented effectively, expeditiously, flexibly, and with stakeholder support.
- Can be shown to have a significant impact on the risks of concern.
- Can be revised and changed when significant new information becomes available, while avoiding "paralysis by analysis."

Every stage of the framework relies on defining risks in a broader context, involving stakeholders, and repeating the process, or part of it, when needed.

materials response teams, emergency room physicians, firefighter rescue teams, and voluntary product recalls.

Every stage of the Framework relies on three key principles:

Broader contexts. Instead of evaluating single risks associated with single chemicals in single environmental media, the Framework puts health and environmental problems in their larger, real-world contexts. Evaluating problems in context involves evaluating different sources of a particular chemical or chemical exposure, considering other chemicals that could affect a particular risk or pose additional risks, assessing other similar risks, and evaluating the extent to which different exposures contribute to a particular health effect of concern. The goal of considering problems in their context is to clarify the impact that individual risk management actions are likely to have on public health or the environment and to help direct actions and resources where they will do the most good.

Stakeholder participation. Involvement of stakeholders—parties who are concerned about or

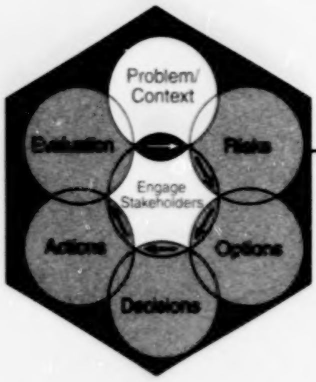
Advantages of the Commission's Risk Management Framework

Traditionally, risk management has relied on command-and-control approaches that often require environmental protection standards to be met using specific technologies. Risk management has generally focused on controlling single hazards in single environmental media. Many risk management failures can be traced to not including stakeholders in decision-making at the earliest possible time and not considering risks in their broader contexts. In contrast, the Commission's Risk Management Framework is intended to:

- ✓ Provide an integrated, holistic approach to solving public health and environmental problems in context.
- ✓ Ensure that decisions about the use of risk assessment and economic analysis rely on the best scientific evidence and are made in the context of risk management alternatives.
- ✓ Emphasize the importance of collaboration, communication, and negotiation among stakeholders so that public values can influence risk management strategies.
- ✓ Produce risk management decisions that are more likely to be successful than decisions made without adequate and early stakeholder involvement.
- ✓ Accommodate critical new information that may emerge at any stage of the process.

affected by the risk management problem—is critical to making and successfully implementing sound, cost-effective, informed risk management decisions. For this reason, the Framework encourages stakeholder involvement to the extent appropriate and feasible during all stages of the risk management process. "Establish a Process for Engaging Stakeholders" on page 15 discusses in depth the value of and approaches to involving stakeholders.

Iteration. Valuable information or perspective may emerge during any stage of the risk management process. This Framework is designed so that parts of it may be repeated, giving risk managers and stakeholders the flexibility to revisit early stages of the process when new findings made during later stages shed sufficiently important light on earlier deliberations and decisions. ("The Importance of Iteration" on page 47 provides more information.)



Defining Problems and Putting Them in Context

The problem/context stage is the most important step in the Risk Management Framework. It involves:

1. Identifying and characterizing an environmental health problem, or a potential problem, caused by chemicals or other hazardous agents or situations.
2. Putting the problem into its public health and ecological context.
3. Determining risk management goals.
4. Identifying risk managers with the authority or responsibility to take the necessary actions.
5. Implementing a process for engaging stakeholders.

These steps are all important, but may be conducted in different orders, depending on the particular situation. For example, when a state or federal regulatory agency is mandated to take the lead on a problem, the steps often will proceed in the order listed above, with the identity of the risk managers already clear, since the state or federal agency will have assumed that role from the start. On the other hand, if the group or individual discovering the problem is not in a position to be the risk manager or to characterize the problem, stakeholders might have to engage in a collaborative stakeholder process to identify risk managers with the needed authority before the other steps can take place. Each step in the problem/context stage of the risk management process is described below.

1. Identify and Characterize the Problem

An environmental or human health problem may already be well recognized or may be a potential problem. Ideally, potential problems will be anticipated and addressed at a very early stage. Problems may be identified through a range of indicators, using such methods and events as:

- Emissions inventories; including the Toxic Release Inventory.
- Environmental monitoring; for example, measuring concentrations of solvents that pollute ground water.
- Biological monitoring; for example, measuring children's blood lead levels or anemia.

A good risk management decision addresses a clearly articulated problem in its public health and ecological context.

- Toxicity testing in laboratory animals to help identify chemicals that might pose risks to humans or ecosystems.
- Toxicity testing using sentinel species in the environment to help identify the impacts of pollution on ecosystems.
- Disease surveillance; for example, observing increases in the occurrence and severity of asthma or noting regional differences in the rates of a particular cancer or birth defect.
- Epidemiologic studies; for example, observations of workplace exposures and particular disease rates.
- Lack of compliance with local or national standards to control contaminant concentrations in air, water, soil, or food.

- A permit application or a violation of a standard or permit (e.g., facility siting, wastewater discharge).
- A bad odor, as in communities where gasoline additives (oxygenated fuels) were used to reduce carbon monoxide emissions from automobiles.
- Community reaction, as may result when a decision is made to build a municipal solid waste incinerator in a neighborhood that was not consulted about the decision.
- Media or environmental activist reports that arouse public concern about a risk based on preliminary or incomplete information.

Potential problems may take some searching to identify.

Characterizing a problem involves investigating what is causing the problem and who or what is affected. For example, characterizing an environmental problem could involve identifying which pollutants or other stressors (such as sediment in a stream) are causing the problem, determining the sources of the pollutants or other stressors, and then determining which human and/or ecological populations are affected. While problem identification may be performed by an individual stakeholder (including the risk management authority), problem characterization should be performed in collaboration with other stakeholders. Here are some questions to ask when characterizing a problem:

Hazard

- What is the problem? Why is it a problem? How was it first recognized?
- What types of adverse effects might the problem cause? Are they reversible?
- How imminently might the effects be experienced? In other words, are the effects likely to appear in the near future, later on in life, or in future generations? How urgent is the need for action? For example, a tank car carrying flammable solvents that overturns in a suburban neighborhood requires immediate attention (and therefore does not require implementation of this Framework); a municipal solid waste incinerator operating normally in the same neighborhood can be assessed more deliberately.
- How do stakeholders perceive the hazard? Do different groups of stakeholders have different perceptions and concerns? For example, parents of children at risk from exposure to an industrial pollutant may feel quite differently about a hazard than workers whose income depends on the facility causing the problem. When these are the same people—that is, the parents are also the workers—perceptions of the hazard can be quite complex.

Exposure

- Who may be exposed? Does the exposure pose different risks to different groups? For example, are the elderly, children, immunosuppressed individuals, or certain ethnic groups at greater

Children can experience higher exposures to pesticides than adults because they eat larger amounts of fruits and vegetables for their size.

risk than others due to age, medical, genetic, or socioeconomic factors, diet, or activity patterns?

- What are all of the relevant sources of exposure? How much does each source contribute to the problem?
- Are the exposures likely to be short term or long term? What is their frequency?

Problem characterization may be iterative, requiring several attempts at refinement as new information is gathered. For example, stakeholders joining the process may bring important information or insights that could modify a characterization or suggest additional lines of investigation. Early iterations might focus on research and education, while later iterations focus on specific pollution reduction measures.

How the problem is characterized will have a tremendous impact on the focus and likely outcome of the risk management process. For example, a problem related to waste disposal capacity could be characterized:

- By waste haulers as the result of inadequate landfill space.
- By local government officials as inadequate recycling of residential or industrial waste.
- By environmental advocates as too much waste generation.

If a problem is characterized too narrowly or incorrectly, risk managers and other stakeholders will invest their resources in exploring and implementing solutions that will be inadequate, less effective, or more costly for reducing risk than they might have been. Also, inappropriate solutions can produce unintended consequences. For example, tightening solid waste disposal regulations can lead to an increase in illegal dumping. In the case of Superfund site cleanups, Resource Conservation and Recovery Act regulations have engendered disposal methods that pose even greater risks than the Superfund sites themselves. Therefore, it is very important to consider the full context of the problem, as described below, before proceeding with other stages of the risk management process.

2. Carefully Consider the Context

A full understanding of the context of a risk problem is essential for effectively managing the risk. Yet historically most risk management has occurred in an artificially narrow context that considers just one chemical, one environmental medium, and one risk at a time. Because this narrow context does not reflect the true complexities of risk situations, it results in risk management decisions and actions that are less effective than they could be. The Commission's Framework expands the context of risk management by including a step in the opening stage, described here, to explicitly consider and define a comprehensive context for a specific risk that is broadly reflective of real-life risk situations. To do this, risk managers and stakeholders must systematically consider several key dimensions of the risk's context:

Multisource context. *Is the population exposed to the same pollutant from other sources?* For example, a local community might be concerned about breathing pollutants such as hydrocarbons and particles released to the air from a nearby power plant, but it might also be breathing hydrocarbons and particles from motor vehicle exhaust, wood stoves, secondhand tobacco smoke, or other sources. (See "The Multi-

Understanding the context of a risk problem is essential for effectively managing the risk.

source Context: Air Toxics" and "The Multisource Context: Residual Risks from Petroleum Sources" on pages 11 and 12 for elaboration.)

Multimedia context. *Is exposure to the pollutant also occurring from other environmental media?* In the power plant example, the community members who are concerned about breathing pollutants could also be exposed to them from food, water, or soil. Other sources of hydrocarbons could be food (such as broiled meats) and soil (resulting from cumulative contamination from decades of emissions from the power plant, vehicles, and other sources). (See "The Multimedia Context: Residual Risks From Secondary Lead Smelters" on page 12 for elaboration.)

Multichemical context. *Do other pollutants from the same sources pose additional risks to the population of concern? Do the pollutants interact? Are their effects cumulative?* In the power plant example, other air pollutants may pose risks for similar adverse effects or may produce different effects when in combination than they do alone. For example, hydrocarbons are usually attached to very small particles, which can increase the risk of cancer from hydrocarbons alone and which can interact with ozone and other air pollutants to form smog.

Multirisk context. *How great a risk does the problem pose compared to other similar risks that the community faces from environmental chemicals?* For example, the risks of respiratory disease associated with exposure to power plant emissions might be compared with the risks of diseases associated with exposure to heavy metals from local municipal solid waste incinerator emissions and the risk of neurological disorders resulting from exposure to a local drinking water source that is contaminated with industrial solvents. ("The Multirisk Context: Ecological Degradation" on page 13 provides an ecological example.)

There may be even broader public health or ecological contexts that local governments and public health agencies have to confront and weigh against chemical exposures—for example, a high incidence of HIV or other infections, a low rate of childhood vaccination, a high drug use and crime rate, or a high rate of alcoholism and its contribution to liver disease, birth defects, and injuries from automobile accidents.

In the power plant example, the initial problem is defined as the health risks posed by air pollutants emitted by a particular type of industrial facility in a particular geographic area. The multisource context would involve identifying other sources (e.g., other types of industrial facilities, motor vehicles) that emit

The broad context of risks in this community include an industrial facility, motor vehicles, lead paint, and contaminated soil.

A problem's context can include other chemicals and other environmental media, and other risks.

those same pollutants to the air in the same geographic area. The multimedia context would involve identifying other environmental media that serve as local pathways of exposure to the same pollutants. The multichemical context would involve comparing the risks from those particular pollutants with the risks associated with other important air pollutants from the same source, such as sulfur oxides and nitrogen oxides. Finally, the multirisk context could consider risks posed by water contamination and solid wastes in the area, and sometimes, other risks to public health.

An initial problem might also be identified and evaluated on the basis of a particular health effect instead of on the basis of contaminant emissions. For example, the increasing incidence and mortality rates of asthma could be addressed. The reasons for the increases are not known, but likely candidates include sulfur oxides, smog, particles, and second-hand tobacco smoke.

The relevant contexts that are identified and characterized after these considerations, and the rationale for their identification, should be incorporated into the risk analysis (see "How Should Risks be Analyzed?" on page 24).

The Multisource Context: Air Toxics

Under the 1990 Clean Air Act, EPA is required to promulgate maximum available control technology (MACT) standards for major sources of hazardous air pollution. MACT standards reduce, but don't necessarily eliminate, air pollutants from these sources. For this reason, the Clean Air Act requires EPA to assess the residual risk caused by the air emissions that will remain after MACT standards are implemented.

Several types of industrial facilities that emit the hazardous air pollutants benzene, 1,3-butadiene, formaldehyde, and acetaldehyde will require MACT standards. A 1993 EPA study of the risks associated with motor vehicle emissions of these same pollutants provides an important context for evaluating the residual risk from those facilities.

Motor vehicles contribute 60%, 94%, 33%, and 39% of the nationwide total of benzene, 1,3-butadiene, formaldehyde, and acetaldehyde air pollution, respectively. EPA estimated the cancer risk of these pollutants for the years 1990, 2000, and 2010. For the 1990 estimate, EPA assumed that 1990 automotive technology was in place. For the 2000 and 2010 estimates, EPA assumed that a number of controls would be in place, including those required by California's stringent emissions standards and a requirement that reformulated gasoline be used by vehicles in all areas of the country that do not attain the current national ambient air quality standard for ozone.

Benzene, formaldehyde, and acetaldehyde from motor vehicles were each estimated to cause no more than 30 additional cases of cancer nationwide per year in any of the years evaluated, while 1,3-butadiene was estimated to cause no more than 300. (At present there are more than 500,000 new cases of cancer each year in the United States.)

The fact that air toxics from industries properly controlled under MACT standards are not likely to be the major sources of cancer risk will be an important context for EPA to consider when the residual risks from industries are assessed and compared to risks from other sources of cancer and respiratory disease. This situation reinforces the need to view all air pollution risk management activities in one context. Both EPA and California have started to do just that by developing integrated air toxics strategies.

The Multisource Context: Residual Risks From Petroleum Sources

In July 1994, EPA promulgated a MACT standard for petroleum refinery emissions. That standard was based partly on EPA's finding that benzene in refinery emissions poses a potential leukemia risk to exposed populations. The standard will reduce, but not eliminate, the benzene and other hazardous air pollutants emitted by petroleum refineries.

Once the standard is implemented, a series of local and regional risk assessments will be conducted to determine whether the remaining benzene in emissions from individual petroleum refineries may pose a leukemia risk in their local area. At this stage it will be important to consider other sources of benzene in air. In fact, motor vehicle emissions are the largest single source of airborne benzene in the United States. When assessing the residual risk from benzene in refinery emissions in a particular region, the benzene risk from refinery emissions could be compared with the benzene risk from mobile sources and any other important benzene emission sources in the area—including benzene in cigarette smoke and from consumer products used at home. It would be appropriate for stakeholders to identify who has responsibility for controlling the other sources.

If the residual leukemia risk from refinery emissions is significant compared to the leukemia risk contributed by other sources, risk-reduction efforts should focus on further reducing refinery emissions. However, if the refinery risk proves insignificant, risk reduction might better be directed at other sources. The overall goal should be to direct risk management resources where they will do the most good to protect or improve the community's health.

A situation in which the multisource context was ignored, with unfortunate results, arose in New Jersey. Benzene is a contaminant found in the air and sometimes the groundwater near marine oil terminals. Benzene levels were measured inside homes near a marine oil terminal and, because the levels were believed to be unsafe, residents were evacuated. In fact, the benzene levels were well within the range found in homes nowhere near any external source, but residents have refused to return to their homes, property values have decreased substantially, and a great deal of community discord persists.

The Multimedia Context: Residual Risks from Secondary Lead Smelters

EPA promulgated MACT standards for secondary lead smelters to reduce human exposure to arsenic, lead, and other pollutants in smelter emissions. Assessing residual risk was difficult because few site-specific data were available on exposure to smelter emissions. To compensate for this data gap, EPA performed a screening risk assessment that relied on many assumptions.

Arsenic. Arsenic causes skin disorders and can increase lung cancer risk. EPA's screening assessment indicated that residual arsenic emissions 100 meters from a smelter would be about one hundred times the average air concentration of arsenic in the United States and about one thousand times the maximum exposure level that EPA

considers to pose negligible risk. An examination of other major sources of arsenic exposure (principally seafood consumption and smoking), however, indicates that smelter emissions actually account for only one-tenth of exposure to arsenic for people living 100 meters from the smelter. Thus, the total exposure context raises a broader risk management issue about what actions should be taken to reduce exposure from all sources. The first step should be to measure actual arsenic concentrations in air around the smelter to compare more accurately the contributions of all sources of arsenic.

Lead. Exposure to lead can cause brain damage. Children are particularly vulnerable. EPA's screening risk assessment found that exposure to lead emissions 100 meters from a secondary lead smelter would be about ten times greater than both the national ambient air quality standard for lead and the average concentration of lead in the United States. Although there are many other sources of human exposure to lead, an analysis of total exposure around the smelter shows that the smelter itself is by far the primary contributor. Thus, in the case of lead the total exposure context confirms that smelters should be the leading target for risk reduction in those communities. Monitoring children's blood lead levels would be a good first step to help guide risk management actions and to evaluate their results.

The Multirisk Context: Ecological Degradation

Many problems not only have multiple sources (the multisource and multimedia contexts), but also are interdependent with other problems (the multirisk context). For example, degradation of watersheds typically is caused by a variety of sources that may include specific industrial discharges, urban and agricultural runoff, land-disturbance activities such as logging and grazing, diversion of water for domestic and agricultural use, overfishing, the introduction of exotic species, and deposition of air pollutants into water. In such cases, risk managers *must* consider these problems in multisource and multirisk contexts in order to develop effective solutions.

One example of a problem requiring multirisk analyses and multisource solutions is the decline of salmon populations in the Columbia River Basin. According to *Pacific Fisherman Yearbooks*, the annual salmon and steelhead catch ranged between 25 and 44 million pounds of fish in the early 1900s. By the 1940s, the range had declined to between 13 and 30 million pounds due to overfishing, irrigation, and power dams. Since that time, many believe that the salmon fisheries have been further stressed by nuclear reactors that have contributed radiation, heat, and chemicals to the Hanford Reach of the Columbia River and by population increases that have resulted in pollution from sewage treatment plants, industrial discharges, and runoff. In the tributaries, timber harvesting has in-

creased sedimentation, water temperature, and blockages of important spawning habitats. Salmon populations have continued to decline.

The ecological consequences of this degradation are accompanied by other impacts. For example, the decline in the salmon fisheries has affected the diet, culture, and religious practices of the Yakama Indian Nation. To successfully address the Columbia River's degradation, risk managers will need to consider multiple sources of stress and complex risk management strategies.

Risk management goals should be used to guide risk analyses.

3. Identify Risk Management Goals

The goals of risk management are varied. They may be **risk related**, aiming to:

- Reduce or eliminate risks from exposure to hazardous substances.
- Reduce the incidence of an adverse effect.
- Reduce the rate of habitat loss.

They may be **economic**, aiming to:

- Reduce the risk without causing job loss.
- Reduce the risk without reducing property values.

They may involve **public values**, aiming to:

- Protect the most sensitive population.
- Protect children.
- Preserve a species from becoming extinct.

They may also be dictated by statute, policy, or existing regulations.

Risk management goals should be used to guide the next stage of the Framework—Analyzing Risks—but the results of risk analysis may lead stakeholders and decision-makers to redefine those goals. It is important to identify the goals early, so they may serve to guide the rest of the decision-making process.

4. Identify Risk Managers

The risk manager is the person responsible for managing the problem. Who the most appropriate risk managers are in a particular situation will depend on the problem's context. In some situations, such as a regulatory context, it will be obvious to all stakeholders that the responsible regulatory agency should or must manage the problem. In other cases, it may not be obvious, or different stakeholders may have different opinions. If so, the issue of who should be the risk manager or managers must be resolved at this stage of the risk management process. Often, risk management responsibilities can be shared, or evolve with changing circumstances. Sometimes, who the risk manager should be will not become evident until the risk management options are identified.

Many different types of people may be risk managers, including:

Federal regulators	Plant managers
State regulators	Public health officials
Local regulators	Clinicians
Local businesses	Citizens
Industries	

Stakeholders are more likely to accept and implement a risk management decision they have helped to shape.

5. Establish a Process for Engaging Stakeholders

The appropriate numbers and types of stakeholders depend on the situation.

A stakeholder is anyone who has a "stake" in a risk management situation. Stakeholders typically include groups that are affected or potentially affected by the risk, the risk managers, and groups that will be affected by any efforts to manage the source of the risk. The overlap between "Engage Stakeholders" and "Problem/Context" in the Framework hexagon on page 3 is larger and darker than the other overlaps because active stakeholder involvement at this particular stage is the most critical element of the decision-making process.

Who the stakeholders are depends entirely on the situation:

- In the case of a contaminated site, stakeholders would include those whose health, economic well-being, and quality of life are currently affected or would be affected by the cleanup and the site's subsequent use. They would also include those who are legally responsible for the site's contamination and cleanup, those with regulatory responsibility, and those who may speak on behalf of ecological considerations or future generations.
- In the case of an application for a pesticide reregistration, stakeholders would include the pesticide manufacturer, owners of the farms where the pesticide is used, laborers who apply the pesticide, consumers who may be exposed to pesticide residues in foods, scientists who seek further pesticide research funding, trade associations like the Grocery Manufacturers' Association, those who speak on behalf of ecological considerations, and those with regulatory responsibility.
- In the case of a substantial decline in the oyster population in a bay because chemicals have been carried into the bay from farms and roads, stakeholders could include the people who harvest the oysters, retailers, consumers, dairy farmers, pesticide manufacturers, manufacturers of automobile emissions control devices, local communities, those who speak on behalf of ecological considerations, and, of course, those with regulatory responsibility.

Questions that can help identify potential stakeholders include:

- Who might be affected by the risk management decision? (This includes not only groups that already know or believe they are affected, but also groups that may be affected but as yet do not know this.)
- Who has information and expertise that might be helpful?
- Who has been involved in similar risk situations before?
- Who has expressed interest in being involved in similar decisions before?
- Who might be reasonably angered if they are not included?

Guidelines for Stakeholder Involvement

- Regulatory agencies or other organizations considering stakeholder involvement should be clear about the extent to which they are willing or able to respond to stakeholder involvement before they undertake such efforts. If a decision is not negotiable, don't waste stakeholders' time.
- The goals of stakeholder involvement should be clarified at the outset and stakeholders should be involved *early* in the decision-making process. Don't make saving money the sole criterion for success or expect stakeholder involvement to end controversy.
- Stakeholder involvement efforts should attempt to engage all potentially affected parties and solicit a diversity of perspectives. It may be necessary to provide appropriate incentives to encourage stakeholder participation.
- Stakeholders must be willing to negotiate and should be flexible. They must be prepared to listen to and learn from diverse viewpoints. Where possible, empower stakeholders to make decisions, including providing them with the opportunity to obtain technical assistance.
- Stakeholders should be given credit for their roles in a decision, and how stakeholder input was used should be explained. If stakeholder suggestions were not used, explain why.
- Stakeholder involvement should be made part of a regulatory agency's mission by:
  - Creating an office that supports stakeholder processes.
  - Seeking guidance from experts in stakeholder processes.
  - Training risk managers to take part in stakeholder involvement efforts.
  - Building on experiences of other agencies and on community partnerships.
  - Emphasizing that stakeholder involvement is a learning process.
- The nature, extent, and complexity of stakeholder involvement should be appropriate to the scope and impact of a decision and the potential of the decision to generate controversy.

A good risk management decision emerges from a decision-making process that elicits the views of those affected by the decision, so that differing technical assessments, public values, knowledge, and perceptions are considered.

Thus, stakeholders may include:

- Community groups.
- Representatives of different geographic regions.
- Representatives of different cultural, economic, or ethnic groups.
- Local governments.
- Public health agencies.
- Businesses.
- Labor unions.
- Environmental advocacy organizations.
- Consumer rights organizations.
- Religious groups.
- Educational and research institutions.
- State and federal regulatory agencies.
- Trade associations.

Why Is Stakeholder Involvement Important?

Experience increasingly shows that risk management decisions that are made in collaboration with stakeholders are more effective and more durable. Stakeholders bring to the table important information, knowledge, expertise, and insights for crafting workable solutions. Stakeholders are more likely to accept and implement a risk management decision they have participated in shaping. According to a 1996 public opinion poll, 80% of U.S. citizens think that the responsibility for controlling risks should be shared by government, businesses, communities, and individuals and that government at all levels should involve citizens in health and environmental protection.

Stakeholder collaboration is particularly important for risk management because there are many conflicting interpretations about the nature and significance of risks. Collaboration provides opportunities to bridge gaps in understanding, language, values, and perceptions. It facilitates an exchange of information and ideas that is essential for enabling all parties to make informed decisions about reducing risks. Collaboration does not require consensus, but it does require that all parties listen to, consider, and respect each other's opinions, ideas, and contributions.

The Commission acknowledges concerns that the costs and additional time needed to involve stakeholders in risk management can be considerable. However, risk management by government agencies has generally been costly anyway, and investment in stakeholder involvement can bring long-term savings, especially when stakeholder involvement catalyzes win-win solutions or when litigation becomes less likely or less protracted. The U.S. Department of Energy, the U.S. Department of Defense, and several states have reported that including community stakeholders in their decision-making process for cleaning up contaminated sites substantially reduced the overall time and expense required.

How Can Stakeholders Be Engaged?

The Risk Management Framework promotes at least some stakeholder participation at each stage of the risk management process. Every risk management situation has a spectrum of interested and affected parties who have different perspectives, concerns, knowledge, and interests. Some parties are proactive in seeking involvement. Others are not. In all cases, however, risk managers should work to:

- Identify all stakeholder groups as early as possible in the risk management process, beginning with the problem/context stage.
- Determine the optimal process for stakeholder involvement.

Incentives for stakeholders to become involved might be helpful in some cases. For example, some community stakeholders have received child care and transportation expenses or funding for technical reviews. Some industry stakeholders could be attracted by the potential for reduced reporting requirements or more efficient permitting. Sometimes, industry stakeholders cover the expenses of community stakeholders through mechanisms such as community advisory groups.

Not all risk management decisions will benefit from extensive stakeholder collaboration. The nature and complexity of stakeholder involvement should be consistent with the:

- Complexity, uncertainty, impact, and level of controversy associated with the decision to be made.
- Urgency with which the problem must be addressed.
- Extent to which participants can have a genuine influence on the decision. If the decision is really not negotiable, stakeholders' time should not be wasted.

There are no hard-and-fast rules for stakeholder involvement. Research on stakeholder involvement

Seven Benefits of Engaging Stakeholders

1. Supports democratic decision-making.
2. Ensures that public values are considered.
3. Develops the understanding needed to make better decisions.
4. Improves the knowledge base for decision-making.
5. Can reduce the overall time and expense involved in decision-making.
6. May improve the credibility of agencies responsible for managing risks.
7. Should generate better accepted, more readily implemented risk management decisions.

is in its early stages, so we are still learning what works, what doesn't work, and why. Nonetheless, a number of guidelines were developed on the basis of the experiences to date that practitioners shared with the Commission, which seem basic to effective stakeholder involvement. Those guidelines are described in the box on page 16 ("Guidelines for Stakeholder Involvement").

Successfully Engaging Stakeholders: San Francisco Bay/Delta Accord

Declaring "a major victory of consensus over confrontation" on December 14, 1994, California Governor Pete Wilson and Cabinet-level federal officials announced the signing of an historic agreement to protect the San Francisco Bay/Delta estuary—the largest and most productive estuary on the West Coast. Known as the Bay/Delta Accord, the agreement was negotiated by the leadership of the state's environmental, urban, and agricultural interests. The accord broke decades of gridlock on California water policy issues by establishing an integrated, ecosystem based approach to protecting the estuary while providing more reliable supplies to the state's urban and agricultural water users.

The collaborative process that led to the accord marked a sharp departure from the decision-making approach traditionally used under the Clean Water Act and Endangered Species Act. Rather than issuing proposals developed by individual agency experts for formal public comment and review, the agencies worked together with environmental, urban, and agricultural interests over two years to identify common goals and mutually acceptable solutions. The final standards were developed through an extensive peer-review process that involved both local and national experts in estuarine systems. This approach sharply reduced the number of legal and scientific challenges that accompany most major agency decisions, and has been hailed as a national model for solving environmental problems.

Building on the success of this collaborative process, the state and federal agencies and interest groups have continued to work together as part of the new CALFED Bay/Delta Program to develop long-term ecosystem restoration goals. In 1996, the agencies and interest groups reached consensus on a $995 million bond measure that will help finance the ecosystem restoration process and other projects vital to the program's success. The bond was passed by voters in November 1996.

Insufficient Stakeholder Collaboration: Granite City, Illinois

When stakeholders are not included early in the decision-making process, they are more likely to oppose the risk management decision and block its implementation. This has been happening in Granite City, Illinois, since 1993, according to testimony from Mayor Ronald Selph and Alderman Craig Tarpoff. Heavily contaminated with lead by a former smelter, much of the city was designated by EPA as a Superfund site. Based on soil sample analyses and a screening risk assessment model, EPA decided to remove the contaminated soil around 1,200 homes and businesses and haul it away.

Some believe that EPA made this decision without adequately consulting the community. City officials believe that this remedy ignored a number of problems:

- The potential health risks associated with recontamination by fugitive dust from the waste pile remaining at the smelter, which was not going to be removed by EPA.
- The health risks posed by fugitive dust from the trucking lot adjacent to the waste pile (which was also not going to be removed by EPA). This soil was contaminated with 50,000 parts per billion of lead.
- The common presence of lead-based paint in the area, which a local study suggested was the most important source of exposure to lead for children.
- The fact that 95% of the children had blood lead levels below 15 µg/dL.

The industrial facility held responsible for the contamination did not respond to EPA's decision, so the agency sued the facility. The city then filed a petition in the suit because officials felt that neither EPA nor the responsible party represented the best interests of the community. EPA began the cleanup anyway, but was restrained by court order. EPA retained an expert whose analysis supported the agency's choice of remedy and the city retained an expert whose analysis concluded that removing contaminated soil would be fruitless unless the remaining sources of contamination—house paint, the smelter waste pile, and the trucking lot soil—were removed as well. Granite City residents are left confused and caught in the middle—some support the city and some support EPA. Property values have fallen. As of late 1996, the case remains unresolved and is back in federal courts.

> "Local public health agencies can play an important role in the execution of the Commission's Risk Management Framework. In Boston, the Department of Public Health produces neighborhood health reports, which individually describe the health status of 16 neighborhoods. The department asked residents what they thought their priorities were, then set up forums for discussing those priorities and pursuing ways to achieve public health goals. Each year the department updates and expands the reports based on neighborhood needs and priorities."
>
> —Ngozi Oleru, Director,
> Office of Environmental Health,
> Boston Public Health Commission

Involving Stakeholders in Maine

Unsuccessful: An Automobile Inspection and Maintenance Program

A sophisticated emissions testing program for automobiles is considered by many to be one of the most cost-effective strategies for reducing emissions of ozone precursors. In early 1993, Maine was the first state in the Northeast to propose adopting this control strategy. This was Maine's first air pollution control plan that would require compliance by citizens. Maine had not required emissions testing previously, focusing instead on stationary sources as the means by which it met its ozone control requirements.

Maine's Department of Environmental Protection conducted all the necessary administrative procedures to implement the program, but never adequately addressed many of the questions and concerns the public raised about the program. In the end, public opposition became so strong that the department was forced to abandon the program in 1994 after only a few months of implementation.

Involving stakeholders would not have guaranteed success, but certainly would have increased its chances. By involving stakeholders early, state regulatory officials could have helped the public understand the legal requirements of the Clean Air Act and the public health need for the control strategy, and officials could have better understood what issues the state needed to resolve to gain public support.

Successful: A Transportation Policy That Considered Alternatives to Highway Expansion

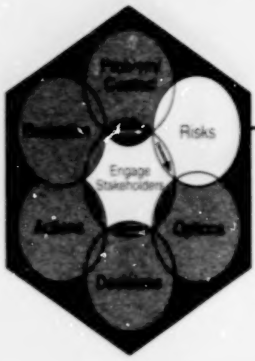
Several years ago, the state of Maine proposed to add lanes to the southern portion of the Maine Turnpike because of significant increases in traffic volume. Citizen opposition was so strong that a referendum was passed, placing a moratorium on turnpike expansion and mandating that the state develop rules requiring the consideration of alternatives to any proposed highway expansion project. Key stakeholders were identified, mobilized, and invited to participate in a negotiated rulemaking, which set up regional, stakeholder-based decision-making committees and criteria for considering alternatives. All agreed that projected traffic volumes did not warrant highway expansion at that time, although such proposals could be considered in the future.

The Important and Synergistic Roles of Regulatory and Public Health Agencies in Identifying and Reducing Environmental Health Risks

The effort to sustain our gains in public health and environmental health protection will be most effective if regulatory and public health agencies work together. Regulatory and public health agencies have important and complementary roles to play in setting policies for environmental health protection and risk management. Yet, in general, these two communities do not interact sufficiently and the connections between environmental exposures and public health are not well established.

The likely synergy between environmental and public health agencies is a reservoir of untapped potential for environmental risk management. Many environmental pollution problems can be identified by their public health contexts. For example, construction of an asphalt batch plant was proposed in Boston. The residents of the urban community in which it was to be constructed were found by public health officials to have a relatively high incidence of asthma and cardiovascular disease. The public health findings signaled a potential environmental health problem that could have been exacerbated by emissions from the asphalt plant. On that basis, construction of the plant was opposed by citizens and by the public health agency, and a decision was made to try to locate the plant elsewhere.

Environmental, public health, and social agencies can work together with community activists to define problems and to develop and implement strategies to manage environmental risks in the full context of poverty, poor schools, and inadequate housing. As our society works to reduce risks in an era of diminishing resources, it is vital that environmental and public health agencies collaborate in deploying the tools of public health—epidemiology, exposure assessment, surveillance, nutrition, genetics, and behavior change—to identify and evaluate the most cost-effective ways to reduce risks and improve public health in all segments of the population. The public health community should accept the challenge to play an influential role in setting national, state, and local priorities and in developing strategies to understand, manage, and prevent environmental risk.



Analyzing Risks

A good risk management decision is based on a careful analysis of the weight of scientific evidence that supports conclusions about a problem's potential risks to human health and the environment.

Why Is Risk Assessment Important?

To make an effective risk management decision, risk managers and other stakeholders need to know what potential harm a situation poses and how great is the likelihood that people or the environment will be harmed. Gathering and analyzing this information is referred to as *risk assessment*.

The nature, extent, and focus of a risk assessment should be guided by the risk management goals. The results of a risk assessment—along with information about public values, statutory requirements, court decisions, equity considerations, benefits, and costs—are used to decide whether and how to manage the risks.

Risk assessment can be controversial, reflecting the important role that both science and judgment play in drawing conclusions about the likelihood of effects on human health and the environment. Often, the controversy arises from what we don't know and from what risk assessments can't tell us, because our knowledge of human vulnerability and of environmental impacts is incomplete, especially at the relatively low levels of chemical exposure commonly encountered in the general community.

How Should Risk Be Characterized?

Risk results from a combination of hazard and exposure. Hazard is an intrinsic property of a substance or situation: for example, benzene can cause leukemia but not lung cancer; DDT can prevent eagles from reproducing in the wild, but does not affect prairie dogs; a rattlesnake bite can kill but a garter snake bite does not. Exposure means contact between the hazardous substance and a person, population, or ecosystem. The more exposure, the greater the risk. When there is no current or potential exposure, there is no risk.

Risk assessment is performed by considering intrinsic hazards, the extent of exposure to the hazards, and information about the relationship between exposures and responses. Unfortunately, we seldom have enough information to accurately determine hazards, exposures, or exposure-response relationships, so risk assessors must use a combination of scientific information and their best judgment to characterize risks. Making judgments about risk on the basis of scientific information is called "evaluating the weight of the evidence." For example, considerations involved in analyzing the weight of the evidence associated with identifying a hazard using toxicity studies in rodents include the:

- Quality of the toxicity study.
- Appropriateness of the toxicity study methods.
- Consistency of results across studies.
- Biological plausibility of statistical associations.
- Similarity of results to responses and effects in humans.

It is important that risk assessors respect the objective scientific basis of risks and procedures for making inferences in the absence of adequate data. Risk assessors should provide risk managers and other stakeholders with plausible conclusions about risk

Risk is determined by considering the nature, likelihood, and severity of adverse effects on human health or the environment.

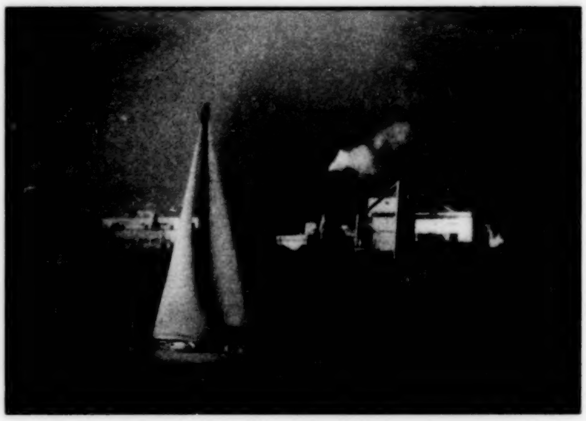
that can be made on the basis of the available information, along with evaluations of the scientific weight of evidence supporting those conclusions and descriptions of major sources of uncertainty and alternative views.

The outcome of a risk assessment is called a risk characterization. Typically a risk characterization should address the following:

- Considering the hazard and the exposure, what is the nature and likelihood of the health risk?
- Which individuals or groups are at risk? Are some people more likely to be at risk than others?
- How severe are the anticipated adverse impacts or effects?
- Are the effects reversible?
- What scientific evidence supports the conclusions about risk? How strong is the evidence?
- What is uncertain about the nature or magnitude of the risk?
- What is the range of informed views about the nature and probability of the risk?
- How confident are the risk analysts about their predictions of risk?
- What other sources cause the same type of effects or risks?
- What contribution does the particular source make to the overall risk of this kind of effect in the

How Should Risks Be Analyzed?

- Clarify the factual and scientific basis of the risks posed by the problem, treating health and ecological risks both qualitatively and quantitatively. Describe the nature of the adverse effects, their severity, and their reversibility or preventability. Identify who is at risk and when they are at risk, and explain the possibility of multiple effects. Evaluate the weight of the scientific evidence and identify the primary sources of uncertainty. For ecological risks, consider indirect effects on human health through disruption of the environment and possible effects on future generations.
- With input from the problem/context stage, put the specific risks posed by the problem into their multisource, multimedia, multichemical, and multirisk contexts.
- Identify stakeholder perceptions of the risks posed by the problem.
- Combine information on the scientific and contextual aspects of the risks posed by the problem into a characterization of the problem's risks to human health or the environment. Include descriptions of stakeholder perceptions and any other social or cultural impacts of the problem.



We lack sufficient animal data on many substances, however, drawing conclusions about human risks from laboratory animals is uncertain.

affected community? To the overall health of the community?

- How is the risk distributed in relation to other risks to the community?
- Does the risk have impacts besides those on health or the environment, such as social or cultural consequences?

The level of detail considered in a risk assessment and included in a risk chacterization should be commensurate with the problem's importance, expected health or environmental impact, expected economic or social impact, urgency, and level of controversy, as well as with the expected impact and cost of protective measures.

Risk characterizations should include sufficient information to enable:

- *Risk managers* to make a useful risk management decision.
- *Stakeholders* to understand the importance and context of that decision.

Stakeholders' perception of a risk can vary substantially depending on such factors as the extent to which they are directly affected, whether they have voluntarily assumed the risk (as in choosing not to wear a seatbelt) or had the risk imposed on them (as in exposure to air pollutants), and whether they are connected with the cause of the risk. For this reason, the Commission recommends that a risk assessment characterize the scientific aspects of a risk and note its subjective, cultural, and comparative dimensions (see "How Should Risks Be Analyzed?" on page 24). While this expands risk assessment beyond its traditional, more narrowly scientific scope, including these additional dimensions will help educate all stakeholders about key factors affecting the perception of risk. Such education is likely to reduce controversy and litigation and to improve communication during the risk management process.

Risk characterizations must include information that is useful for all stakeholders.

Risk characterization should form a common basis for the understanding of a problem among stakeholders. Stakeholder involvement within the Risk Management Framework should enhance the integrity of the risk assessment. Stakeholders play an important role in providing information that should be used in risk assessments and in identifying specific health and ecological concerns they would like to see addressed. For example, community stakeholders consulted at this stage can help identify groups with high exposures so that appropriate exposure assessments can be designed. Industry stakeholders can provide important information about a substance's toxicity and lifecycle.

The integrity of a risk assessment is best assured if it is carried out or peer-reviewed independently, for example, by scientists at regulatory agencies, universities, and research institutions. To relieve some of the burden on regulatory agencies and other public institutions, however, certification, auditing, and oversight programs should be considered, so that companies, industry organizations, and other organizations or individuals can provide risk assessments that are considered credible by all stakeholders. For example, in order to place greater responsibility on the private sector for cleaning up contaminated sites, the state of Massachusetts has instituted a successful program for certifying Licensed Site Professionals to oversee or perform site assessments or cleanups.

The Need for More Data

Lack of data is a major barrier to reliable risk assessments.

We lack data on the hazards that chemicals and other stressors pose, largely because of:

- The ethical barriers to deliberately exposing humans.
- The limitations of tests in laboratory animals and cell systems.
- The technical uncertainties involved in extrapolating data from laboratory animals or cell systems to humans.
- The difficulties associated with determining differences in susceptibility among people.
- The expense involved in studying hazards.

As a result, many chemicals are never properly tested at all.

We lack data on actual human and ecological exposures to agents of concern, largely due to:

- The privacy issues involved in studying humans directly.
- The substantial cost of the environmental monitoring needed to gather the data.

Because of the difficulties involved in studying chemical hazards and exposures, risk assessors cannot always accurately determine the health risks of an exposed population or the ecologic risks of an exposed ecosystem, the contribution of each individual source of exposure to the overall risk, or the success of risk management actions in reducing the risk from existing sources of exposure.

Ecological Risk Assessment and Risk Management

Human and ecological health are intimately connected. Ecosystems are crucial to human survival and well-being. We depend on them for many things—including material goods (such as food, building materials, and fiber) as well as recreation and spiritual sustenance. Many environmental problems, such as global climate change and hormonally active contaminants, pose an inseparable combination of health and ecological risks.

While many of our laws were intended to protect simultaneously human and ecological health, ecological risk assessment has long been eclipsed by human health risk assessment. In recent years, however, we have begun to recognize the importance of directly protecting ecosystems, rather than indirectly protecting them through measures taken to improve human health. As agencies gain experience in applying the ecological risk assessment process, risk managers will become better equipped to address important ecological problems—such as protecting biological diversity and habitats, maintaining ecosystem health, and guiding sustainable development.

Although the techniques for ecological risk assessment differ somewhat from those of traditional human health risk assessment, the Commission's Framework is designed to be flexible enough to accommodate both.

Assessing aggregate risks from multiple exposures is an area in which risk assessors and risk managers need both methods and experience.

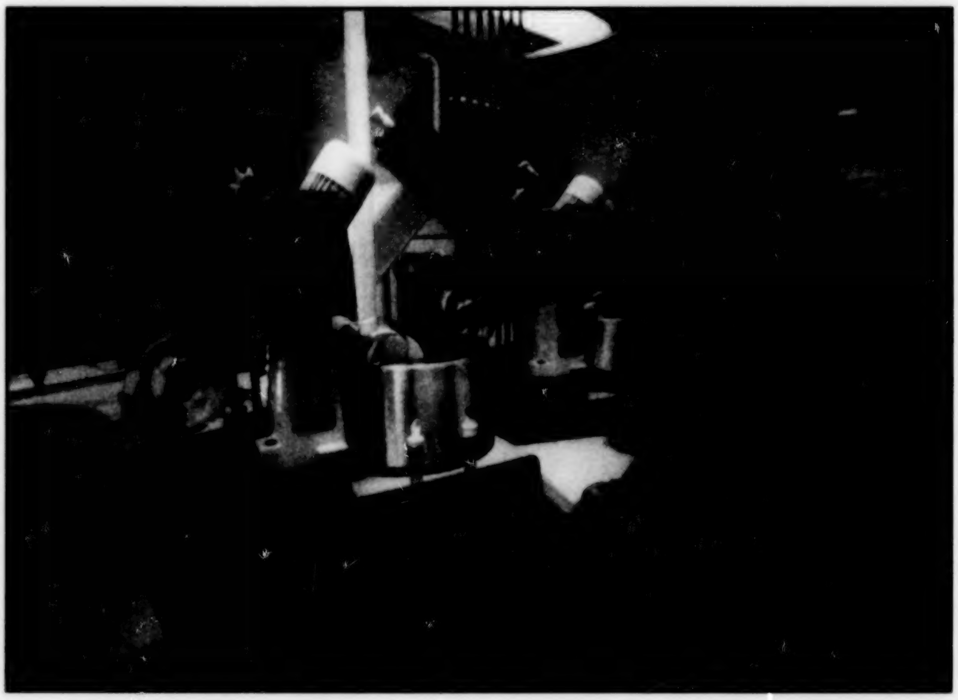
Risk assessment will be greatly improved if risk assessors and other members of the scientific and risk management communities can work to develop and validate new toxicity tests in laboratory animals, investigate similarities and differences in laboratory animals and humans, obtain data on exposures, and develop and validate models to help fill toxicity and exposure data gaps.

The Importance of Comprehensive, Multimedia Risk Analysis

Risk assessment provides the scientific foundation for risk management decision-making. Traditionally, risk assessments, like risk management, have largely focused on assessing the risks of just one chemical in one medium at a time. However, to achieve comprehensive, multimedia risk management, risk managers will need comprehensive, multimedia risk assessments. Thus, to improve risk management, the risk assessment paradigm must be expanded.

A number of EPA offices conduct more comprehensive risk assessments. Specifically, when establishing a standard for exposure to a chemical in drinking water, EPA accounts for nondrinking water sources of exposure to that chemical. When considering whether to reregister a pesticide, EPA now considers other sources of exposure to that pesticide and to similar pesticides. In addition, some total exposure and cumulative exposure studies have been performed. However, few other regulatory agencies consider exposures or risks this comprehensively, and EPA often does not do so because of resource or statutory limitations. Failure to account for multiple and cumulative exposures is one of the primary flaws of current risk assessment and risk management.

To the greatest extent possible, EPA and other regulatory agencies must work to develop and refine techniques for comprehensive risk assessment. In addition to the work already being done by EPA, a number of other efforts provide useful models. One example of a technique for assessing aggregate or cumulative risks from multiple pollutants and multiple sources is the method for regional risk assessment of air pollution developed by the Air and Waste Management Association. This method was used in San Diego as part of

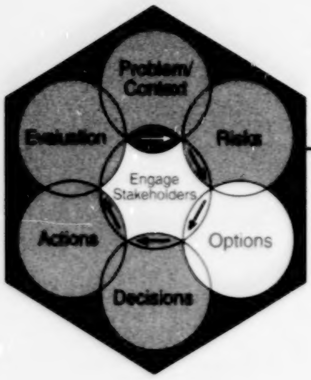


Scientists must develop methods to assess multimedia, multisource, multichemical risks.

Analyzing Risks

California's "hot spots" program, which examines the potential for cumulative pollution from multiple facilities to impact neighborhoods in a county. The method generates a contour map of estimates of the maximum cancer risks associated with industrial facilities throughout the county using meteorological data and information on contaminants, emission rates, and risks from individual facilities. The results can be used to:

- Estimate the relative contribution of individual industrial facilities to the overall regional risk associated with industrial facilities.
- Estimate the relative contribution industrial facilities make to background risks.
- Compare risks from industrial facilities to risks associated with other sources of air pollution, such as motor vehicles.



Examining Options

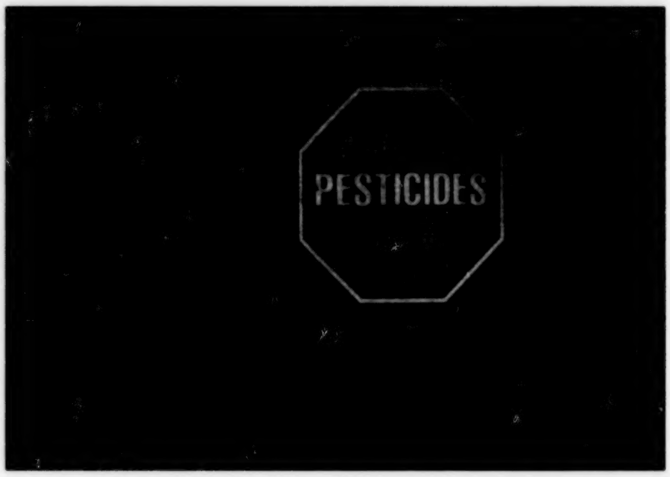
A good risk management decision is made after examining a range of regulatory and nonregulatory risk management options.

This stage of the risk management process involves identifying potential risk management options and evaluating their effectiveness, feasibility, costs, benefits, unintended consequences, and cultural or social impacts. This process can begin whenever appropriate after defining the problem and considering the context. It does not have to wait until the risk analysis is completed, although a risk analysis often will provide important information for identifying and evaluating risk management options. In some cases, examining risk management options may help refine a risk analysis. Risk management goals may be redefined after risk managers and stakeholders gain some appreciation for what is feasible, what the costs and benefits are, and what contribution reducing exposures and risks can make toward improving human and ecological health.

Stakeholders can play an important role in all facets of identifying and analyzing options. They can help risk managers:

- Develop methods for identifying risk-reduction options.
- Develop and analyze options.
- Evaluate the ability of each option to reduce or eliminate risk, along with its feasibility, costs, benefits, and legal, social, and cultural impacts.

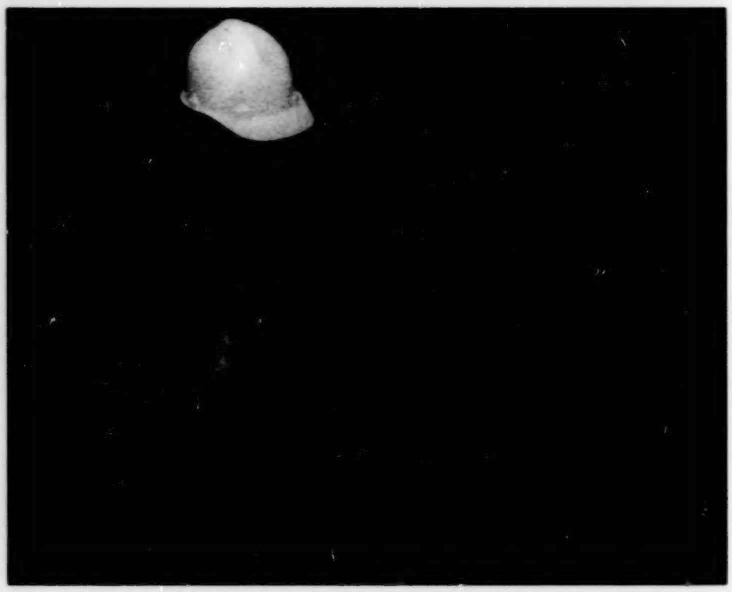
The two components of this stage of the Risk Management Framework—identifying options and analyzing options—are described below. Creativity, imagination, and openness are key to success during this stage.



Identify Options

There are many different regulatory and nonregulatory approaches to reducing risk. These include:

- Encouraging pollution prevention either by reducing or eliminating the use of hazardous agents or by improving technology to reduce the likelihood that they will be released to the environment.
- Limiting pollutant emissions by requiring operating permits for industrial facilities, incinerators, and wastewater treatment plants.
- Taxing industries on the basis of the pollutants they release.



These workers are discussing changes in processing that could eliminate the use of some hazardous chemicals.

- Enforcing compliance, as is done by EPA to ensure cleanup at Superfund sites, by the Department of Agriculture when foods are found to be contaminated with microorganisms, and by the Occupational Safety and Health Administration when workplace exposure limits are exceeded.
- Recycling and encouraging the use of recycled materials.
- Educating/informing affected communities about steps they can take to reduce their risks, such as posting signs warning about contaminated fish, showing workers which workplace practices lead to fewer chemical exposures, and encouraging people to reduce the fat and increase the fruits and vegetables in their diets.
- Establishing market or other incentives for voluntary behavior changes that will reduce risk, such as allowing companies to trade among themselves the amount of pollutants they are permitted to release and requiring facilities that emit pollutants to publicly report the amounts they release.
- Removing the source of risk, such as cleaning up a hazardous waste site, banning a pesticide that prevents birds from reproducing, or removing contaminated food from the marketplace.

During this stage of the Framework, risk managers and stakeholders consider which of these and other types of options may be appropriate. Sometimes only one of these options will seem appropriate. However, a combination of options often will be most effective for reducing risk. (The box "Risk Management Methods" on page 31 provides more information on options.)

Analyze Options

Once potential options have been identified, the effectiveness, feasibility, benefits, and costs of each option must be assessed, along with their potential legal, social, cultural, and political implications, to provide input into selecting an option. Key questions to ask include:

- What are the option's expected benefits?
- What are the option's expected costs?
- Who gains the benefits and who bears the costs? What are the equity or environmental justice implications?
- How feasible is the option, given the available time and resources, as well as legal, political, statutory, and technology limitations?
- Does the option increase certain risks while reducing others?

Risk Management Methods

The number of options for reducing risks to human health and the environment has increased in recent years, providing risk managers with greater flexibility and a wide suite of risk management tools. Historically, risk reduction was most commonly achieved by command-and-control regulations that dictated how to control pollution at the "end of the pipe" rather than reducing or preventing it in the first place. Regulatory requirements were then enforced through a system of permits, penalties, and legal actions. This approach significantly reduced pollution, but may have reached a point of diminishing returns—in other words, further improvement via this approach will likely be very expensive for the additional benefit gained.

For this reason, regulatory agencies have been exploring and implementing a number of regulatory and nonregulatory alternatives in recent years, including education, incentives, monitoring, surveillance, and research:

Education/Information. Educational tools include right-to-know requirements such as EPA's Toxics Release Inventory and California's Proposition 65. These laws require industry to publicly and periodically disclose information about pollution and potentially hazardous products. Right-to-know laws are based on the idea that public concern about pollution will encourage industry to voluntarily reduce the use and release of pollutants and hazardous products.

Incentives. Voluntary risk reduction can be encouraged through a number of mechanisms, including market-based incentives, subsidies, alternative compliance, and consensus, mediation, and dialogue projects. One example of market-based incentives is the use of tradable pollutant allowances in combination with a cap on the amount of pollution released—such as sulfur dioxide in EPA's acid rain program. Alternative compliance projects include EPA's Project XL, which is experimenting with ways to give companies greater flexibility in how they reduce emissions or their related risks to or below target levels.

Monitoring. Monitoring can be a useful risk management tool, especially when a community is skeptical about how effective a risk management option will be. Communities may be more willing to accept an alternative to a traditional command-and-control program when monitoring data provide concrete evidence about its effectiveness.

Surveillance. Health surveillance is a valuable technique for observing the effects of pollution and the expected positive impact of pollution reduction measures, especially in the workplace.

Research. The Risk Management Framework will generate questions and identify gaps in knowledge that must be addressed through research. Research agendas are an important output of risk management processes and are sometimes required by statute, such as the periodic reassessment of evidence underlying national ambient air quality standards required by the Clean Air Act. EPA's cooperative effort with scientists in universities, industries, and environmental groups to identify and design appropriate research projects on hormonally active contaminants is another example of research to inform risk management decision-making.

Examining Options

Recycling and encouraging the use of recycled materials are nonregulatory options.

Expected Benefits/Effectiveness

It is important to determine what the specific intended benefits will be because they will be evaluated at a later stage in the Framework. The most obvious benefit from risk management is risk reduction or elimination. This may take a number of forms, including:

- Improved health, through reduced occurrence of cancer, birth defects, asthma, or other diseases.
- Habitat protection.
- Increased biodiversity.

Other important potential benefits include savings in health care costs, technology development, the economic benefits of exporting new technologies, and the employment opportunities that new technology development and its application can bring. (Technology development can also be considered a cost; see "Expected Costs.")

Because it is often difficult to detect risk reduction in the rates of disease, death, or habitat destruction, indirect methods of evaluating effectiveness and identifying reductions in risk may be necessary. Indirect indicators of risk reduction include reductions in:

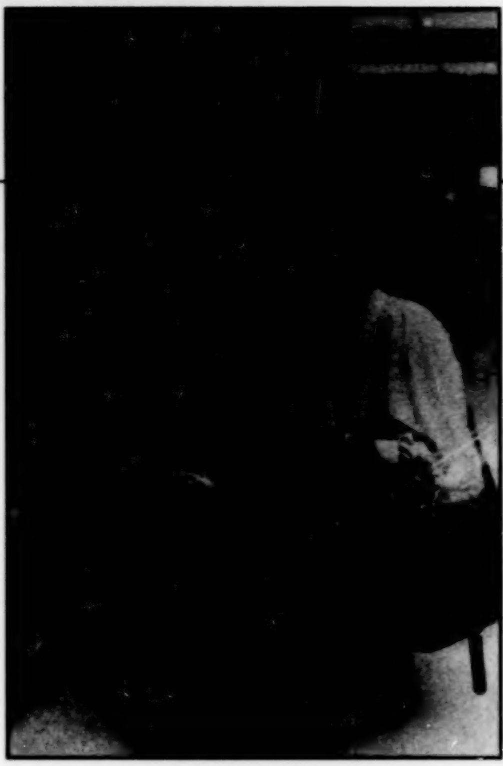
- Pollution-generating activities, such as fewer vehicle miles travelled.
- Contaminant emissions from their sources, for example, at the site of a facility's wastewater discharge point or in stack emissions.
- Contaminant concentrations in environmental media, such as lower ozone, radon, or particulate levels in air; lower concentrations of industrial solvents in ground water; or lower concentrations of heavy metals in soil.
- Contaminant concentrations in other sources of exposure, such as less mercury in swordfish, fewer microorganisms in meat, or pesticide residues on fruit that are below detectable levels.
- The occurrence of particular biological markers of exposure or disease, such as chromium levels in hair, lead levels in blood, or changes in the components of the immune system.

All potential forms of risk reduction should be examined, as well as any other benefits, such as the identification or development of new technologies or approaches for controlling or reducing risks. Indirect measures of risk reduction or elimination are not the real objectives, however; they are only surrogates and are not always reliable. Their validation is difficult. Whenever possible, direct measures of risk reduction or elimination should be used. When indirect measures are used, the uncertainties surrounding their use should be discussed. When the stakes are high, investment in developing and validating direct measures should be considered. The box "Measuring the Effectiveness of a Risk Management Action" on page 47 provides more detail on the challenges of measuring the effectiveness of actions to reduce risk.

Expected Costs

The costs of implementing an option may be monetary and nonmonetary. Monetary costs include the costs of:

- Technology development—researching and developing new engineering processes or equipment.
- Technology application—purchasing, installing, operating, and maintaining equipment needed to



Purchasing bottled drinking water instead of pumping and treating contaminated ground water may be an option.

improve an industrial process or reduce emissions.

- Training needed to use new technology, carry out new procedures, or monitor effectiveness.
- Cleanup—hiring contractors and engineers to implement a remedy at a contaminated site.
- Transportation and infrastructure—removing hazardous materials and trucking them to a disposal site and, sometimes, improving roadways to accommodate the increase in heavy vehicle traffic.
- Health care, such as that needed for workers responsible for implementing an option that puts them at risk.
- Diversion of investments, or opportunity costs—such as having to spend money on environmental controls instead of using those resources to build a school or reduce taxes.

Nonmonetary costs include the costs of:

- Valued environmental assets lost, such as recreation areas, endangered species, visual range, open space, and wetlands.
- Flexibility and choice for consumers and businesses lost because certain products, practices, or processes are no longer available or permitted.
- Decreased sense of well-being or security.

Both types of costs should be considered when evaluating options. As with estimates of risks and benefits, however, cost estimates are uncertain. It is important to obtain independent and defensible cost estimates to the extent possible. See the section "Linking Risk and Economics" on page 36 for more perspective on evaluating costs.

Distribution of Benefits and Costs

Evaluations of costs and benefits have been criticized because they are often blind to issues of environmental equity and fail to make explicit who bears the costs of a risk management decision and who gains the benefits. For example:

- If a new policy is instituted that limits the application of a widely used pesticide, the cost of certain fruits and vegetables could increase significantly. Should this occur, those who still can afford to buy those fruits and vegetables may benefit by enjoying reduced health risks from pesticides. However, economists argue, others who can no longer afford those fruits and vegetables may suffer poorer nutrition and increased cancer risk associated with eating too few fruits and vegetables.
- In Boston, a freeway exit ramp was proposed to make commuting more convenient for office workers. However, because of its location, the new ramp would have substantially increased exposure to air pollutants experienced by residents of Chinatown, a densely populated neighborhood.

As these examples illustrate, understanding and evaluating potentially inequitable costs and benefits is important for making risk management decisions.

Feasibility

The feasibility of an option can be constrained by a variety of technological, legal, political, economic, and other issues. When an option is examined, the feasibility of actually implementing it should be an important evaluation criterion. For example, the feasibility of implementing a technological option may be limited by the availability of the technology or by its cost; implementing administrative options such as setting up a recycling program or providing incentives may be constrained by political or legal barriers. Regulated parties often debate an option's feasibility; however, options that are technologically infeasible today frequently can, through technology development or policy change, become feasible in the future.

Stakeholders and EPA Identify Risk Management Options for the Pulp and Paper Industry

In 1990, EPA assembled a team of experts in air and water pollution to formulate integrated rules to control water discharges and air emissions from the pulp, paper, and paperboard industry. A screening assessment of 104 mills that use chlorine as the bleaching agent for paper had found dioxins and furans in the mills' water discharge, sludge, and pulp at levels that have the potential to harm fish and wildlife and to cause cancer and other health effects in humans.

Before deciding how best to reduce these discharges, EPA held meetings, conference calls, and a symposium to seek views and information from many stakeholders—including individual companies, an industry association, consultants, vendors, labor unions, and environmental organizations. EPA shared its data and thinking about various approaches with stakeholders *before* publishing proposed rules in the *Federal Register*. Even the preamble to the proposed limitations and standards was reviewed by stakeholders before being published. In all, five public meetings were held before the proposed rule was published in 1993 and one afterwards.

During the many discussions of control options, environmentalists pressed for a "totally chlorine-free" option to eliminate the discharge of chlorinated pollutants. EPA proposed a technology option. Industry asked EPA to consider a second option they considered more feasible. EPA assessed potential compliance costs, effluent reduction benefits, economic and environmental impacts, management practices, recovery systems, and equipment availability. The agency then proposed both technology options as well as a voluntary incentives program to encourage and reward individual mills that implement "totally chlorine-free" technologies. While not everyone is happy with the proposals, stakeholder involvement improved the development of options.

Consideration of health care costs may be an important factor in balancing costs and benefits.

Potential Adverse Consequences

Analysis must consider whether an option may cause any adverse consequences. One of the most important is the potential for an option to increase one type of risk while reducing the risk of concern:

- While reducing pollutant concentrations in one environmental medium, the option may increase pollutants in another medium. For example, using aeration reduces pollutants in drinking water by releasing them to the air. (Of course, if exposure to air is considerably less than exposure to drinking water, this tradeoff may be worthwhile.)
- While reducing long-term health risks for community members, an option may produce short-term health risks and injury for workers, as can happen during cleanup of sites contaminated with hazardous chemical and radioactive wastes.
- Banning one pesticide because it might cause cancer may increase the use of another pesticide that is known to cause birth defects or to harm wildlife, or whose health effects are not known.

Thus, tradeoffs among different risks must be identified and considered.

Together with social and cultural considerations and information on risks to health and the environment, economic analysis can provide important input to risk management and regulatory policy decisions.

Other adverse consequences may be cultural, ethical, political, social, or economic, such as:

- Economic impacts on a community, including reduced property values or loss of jobs.
- Environmental justice issues, such as inequitable distribution of costs and benefits as mentioned above; disregard for a particular population group's dietary needs, preferences, or nutritional status; or giving priority to site cleanup efforts in more affluent areas.
- Harming the social fabric of a town or tribe by relocating the people away from a highly contaminated area.

Linking Risk and Economics

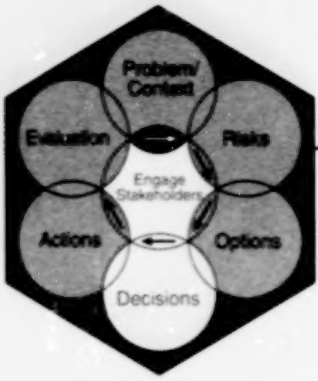
In addition to considerations of risk, public values, and legal requirements, economic analysis can play an important role in the Risk Management Framework. For example, cost-effectiveness analysis can help identify the least costly risk management option for reaching a particular goal. And, by clarifying who bears the costs and who gains the benefits, economic analysis can help identify inequities.

Economic analysis has strengths and limitations, and its role in regulatory decision-making is controversial. Three common concerns are that:

- Economic analysis places too much emphasis on assigning dollar values to aspects of health and the environment that are difficult, if not impossible, to quantify in monetary terms.
- Regulatory decisions about health and environmental protection might be based strictly on whether the estimated monetized, quantifiable benefits outweigh the estimated quantifiable costs.
- The results of economic analyses are often conveyed in a manner that ignores assumptions and uncertainties, giving the impression of far greater precision than is generally possible or appropriate.

Another problem is the inconsistency between the way risk assessors estimate risks and what economists need to know about risks in order to evaluate risk-reduction alternatives.

Nevertheless, the tools of economic analysis, when appropriately used, are legitimate and useful ways to provide information for risk managers making decisions that will affect health and the environment. Economic analysis should not be used as the sole or overriding determinant of those decisions, however. Information about costs and benefits that cannot be assigned monetary values also must be explicitly considered, along with information about risks and social and cultural concerns. Peer review should play a critical role in evaluation of the quality of economic analyses and the technical information underlying them.



Making a Decision

> **A good risk management decision reduces or eliminates risks in ways that:**
>
> - Are based on the best available scientific, economic, and other technical information.
> - Account for their multisource, multimedia, multichemical, and multirisk contexts.
> - Are feasible, with benefits reasonably related to their costs.
> - Give priority to preventing risks, not just controlling them.
> - Use alternatives to command-and-control regulation, where applicable.
> - Are sensitive to political, social, legal, and cultural considerations.
> - Include incentives for innovation, evaluation, and research.

Who Decides?

During this stage of the Framework, decision-makers review the information gathered during the analyses of risks and options to select the most appropriate solution. When the risk problem falls under the purview of a federal, state, or local regulatory authority, the regulatory agency makes the risk management decision. Consumers, manufacturers, and others responsible for wastes and pollution also can make socially important decisions to reduce or eliminate risks. A productive stakeholder involvement process can generate important guidance for decision-makers. Thus, decisions may reflect negotiation and compromise, so long as statutory requirements and intent are met. In some cases, win-win solutions are available that allow stakeholders with divergent views to achieve their primary goals.

Involving stakeholders and incorporating their recommendations where possible reorients the decision-making process from one dominated by regulators to one that includes those who must live with the consequences of the decision. This not only fosters successful implementation, but can promote greater trust in government institutions.

What Is the Best Decision?

In most risk management situations, decision-makers will have a number of options from which to choose. Which option is optimal depends on the particular situation. Seven criteria, listed above and discussed below, are fundamental characteristics of any sound risk management decision. These criteria echo the key themes that underlie the early stages of the Framework because the goal of the earlier stages is to produce the most relevant and useful information for sound risk management decision-making.

■ *Base the decision on the best available scientific, economic, and other technical information.*

Usually, the technical information that is available on which to base a risk management decision is incomplete. Decision-makers often must rely on:

- Predictions about human hazards that are based on experiments in laboratory animals.
- Predictions about how much exposure occurs in a lifetime based on few or no measurements of the actual levels of exposure.

- Predictions about the risks to entire ecosystems that are based on observations in only one or two species.
- Assumptions and models of exposure, exposure-response relationships, and estimates of the costs and benefits of different options.

Because so many judgments must be made based on limited information, it is critical that *all* reliable information be considered. Risk assessors and economists are responsible for providing decision-makers with the best technical information available or reasonably attainable, including evaluations of the weight of the evidence that supports different assumptions and conclusions.

■ *Be sure the decision accounts for the problem's multisource, multimedia, multichemical, and multirisk contexts.*

Considering a risk in isolation cannot provide decision-makers or the public with any sense of how important the risk is, compared with other risks, or of the impact that reducing or eliminating it might have on overall human and ecosystem health. Considering risks in context can help direct resources toward the risk management actions that will do the most good. As described in the "Problem/Context" section earlier in this report, we need to move away from our current one chemical/one environmental medium/one risk approach toward developing a more comprehensive and holistic appreciation for problems and their contexts, so that meaningful, practicable goals can be developed.

■ *Choose risk management options that are feasible, with benefits reasonably related to their costs.*

Many risk management options may be infeasible for social, political, cultural, legal, or economic reasons (see the "Examining Options" section of this report), or because they do not reduce risks to the extent needed. For example, groundwater remediation using pump-and-treat technology may be infeasible because, for a variety of technical and hydrogeologic reasons, it will not sufficiently reduce contaminant concentrations in the ground water. Removing all the soil from an entire valley that is heavily contaminated with mining waste is infeasible. Expecting everyone to stop driving automobiles is infeasible. On the other hand, the costs of reducing acid rain by controlling power plant emissions are considered justified by their benefits—protecting streams and lakes and reducing damage to automobile finishes and construction materials. Of course, the feasibility and cost-effectiveness of an option may change in the future as technology is improved or as society's values change.

■ *Give priority to preventing risks, not just controlling them.*

If pollutants are not released into the environment, exposure cannot occur. If exposure does not and will not occur, risks will not result. Where feasible, preventing contaminant releases is preferable to removing them or cleaning them up later. Preventing releases can avoid the costs of remediation and health care. Many industries have found that eliminating pollutants can substantially reduce the cost of producing a product.

■ *Use alternatives to command-and-control regulation, where applicable.*

Command-and-control risk management strategies have significantly improved human health and environmental protection. Alternative strategies will enable even greater levels of protection by encouraging industries, municipalities, and other stakeholders to tailor remedies to reflect the circumstances of individual sources and locations.

> "The department has learned the power of having the public involved in decision-making. For example, the citizens advisory board at Fernald has dramatically changed the department's cleanup strategy at that Ohio site. The results will be a far more expeditious cleanup, with a savings of some $2 billion compared with the cost of the department's original plans. By opening the process to meaningful public input, the department is empowered to make decisions it could never make unilaterally."
>
> —Carol Henry,
> Associate Deputy Assistant Secretary
> for Science and Risk Policy,
> U.S. Department of Energy

Encouraging flexibility can result in risk management options that meet or exceed expectations and that are cost-effective. Various alternatives to command-and-control strategies are described in the "Examining Options" section of this report.

- ***Be sensitive to political, social, legal, and cultural considerations.***

The least costly risk management option is not always the most desirable. An option is more likely to be implemented successfully if it takes into account important cultural needs or social impacts (see the discussion of stakeholder involvement in the "Problem/Context" section of this report).

- ***Include incentives for innovation, evaluation, and research.***

Command-and-control risk management strategies that specify technology that must be used or actions that must be taken can fail to stimulate better, cleaner, and more cost-effective approaches. Without evaluation, the success (or failure) of a risk management action and its unintended consequences may not be determined (see the "Evaluating Results" section of this report). Incentives for research are needed to generate knowledge about hazards, exposures, options, and actions.

What Happens If There Isn't Enough Information To Make a Decision?

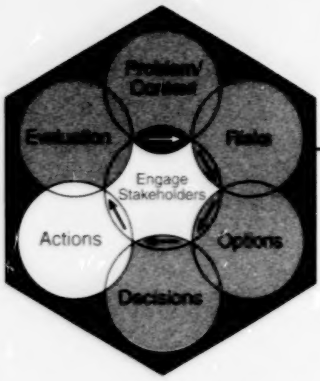
Decision-makers must balance the value of obtaining additional information against the need for a decision, however uncertain. Sometimes a decision must be made under the precautionary principle. Every effort should be made to avoid "paralysis by analysis" where the need for additional information is used as an excuse to avoid or postpone decision-making. When sufficient information is available to make a risk management decision or when additional information or analysis would not contribute significantly to the quality of the decision, the decision should not be postponed. "Value-of-information" techniques can be used to provide perspective on the next steps to be taken.

Making Decisions: Steel Industry

The Clean Air Act Amendments of 1990 required EPA to cut toxic air pollution from iron and steel plant coke ovens. Coke ovens produce the material used in blast furnaces to convert iron ore to iron. Coke oven air emissions were already regulated by the Occupational Safety and Health Administration and states, and by EPA under the hazardous substance notification requirements of Superfund. The issue of how best to reduce coke oven emissions was contentious and had been deadlocked for 20 years.

To break this logjam, EPA initiated a negotiated rulemaking process with extensive stakeholder involvement. Over two years, the Agency met with representatives of industry and industry associations, labor unions, states, and environmental groups in workshops and informal and formal meetings. Negotiators worked with stakeholders to develop a regulation that all parties could support. By making concessions in one area in exchange for others in other areas, the parties resolved such major issues as what emissions data would be used, monitoring methods, numerical emission limits, costs and economics, and work practices. They also identified and discussed emission sources, enforcement and implementation needs, future research, and integrating the proposed regulation with EPA's new permitting system.

The process successfully involved stakeholders in making decisions that had dragged out for decades. The resulting regulation reduces hazardous air pollution by 1,500 tons per year.



Taking Action

Traditionally, implementation has been driven by regulatory agencies' requirements. Businesses and municipalities are generally the implementers. However, the chances of success are significantly improved when other stakeholders also play key roles. Depending on the situation, action-takers may include:

- Public health agencies
- Other public agencies
- Community groups
- Citizens
- Businesses
- Industries
- Unions/workers
- Technical experts

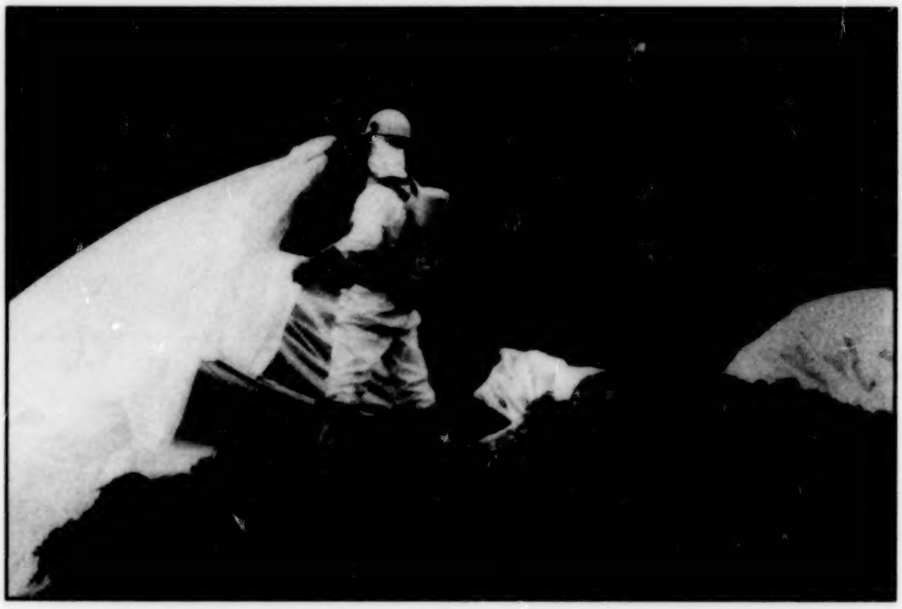
These groups can help:

- Develop and implement a plan for taking action.
- Explain to affected communities what decision was made and why and what actions will be taken.
- Monitor progress.

The box "Examples of Risk Management Actions" on page 42 provides specific examples of risk management activities that stakeholders can perform or assist.

Involving stakeholders in the decision-making process, as set forth in this Framework, not only produces a better risk management decision, but also lays a foundation for stakeholder involvement in implementation. Involved stakeholders are more likely to understand and support the decision and to have developed the relationships, knowledge, communication channels, and administrative mechanisms to work together on implementing the decision.

A good risk management decision can be implemented effectively, expeditiously, flexibly, and with stakeholder support.



This worker is cleaning up a Superfund site.

Examples of Risk Management Actions

- **Public health agencies** educating different cultural, ethnic, and socioeconomic groups about practices to modify or avoid, such as smoking, alcohol consumption, high-fat diets, eating parts of contaminated fish that concentrate pollutants, and chemical or radiation hazards in the home.
- **Municipalities** working to reduce nonpoint sources of pollution, such as runoff from highways, by preventing erosion; upgrading drinking water, sewage, and municipal solid waste treatment facilities; or instituting recycling programs.
- **Community groups** working with local businesses and industries to monitor the success of their risk-reduction activities.
- **Citizens** recycling, purchasing products that use recycled materials, or complying with automobile emissions testing.
- **Businesses** no longer selling products that can harm the environment; disposing of wastes safely; or working with employees to anticipate and reduce worksite safety and health risks.
- **Industries** reducing or eliminating emissions or discharges to ambient air, workplace air, and bodies of water by upgrading air pollution control technology, upgrading wastewater treatment, and improving manufacturing processes (such as developing a closed-system approach, recycling wastes, or substituting less hazardous materials).

- **Unions** working with industries to identify less hazardous workplace practices and processes; educating workers about practices that reduce hazardous exposures in the workplace and hazardous emissions to the environment, such as proper waste disposal; or helping employers monitor the success of risk-reduction activities.
- **Technical experts** providing technical assistance to local agencies, community groups, businesses, and unions to help implement risk-reducing actions.

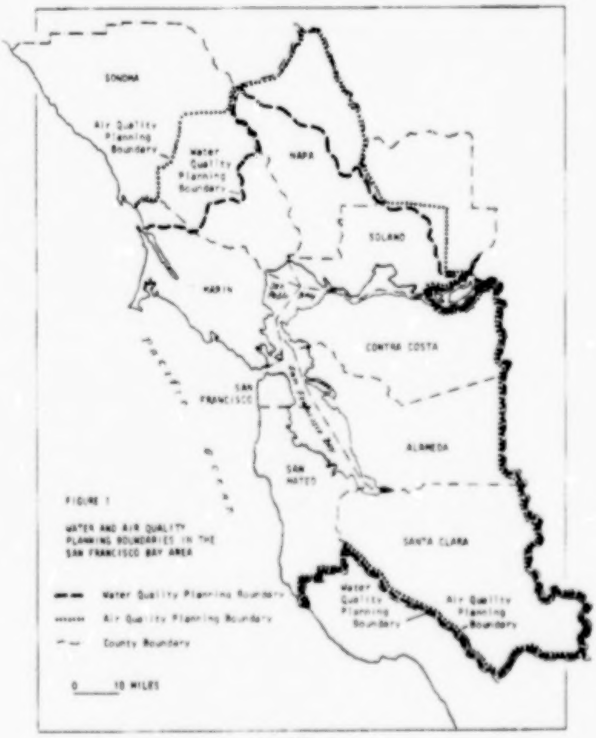
Taking Action: San Francisco Bay

The San Francisco Bay is vulnerable to many sources of pollution. In 1978, the Association of Bay Area Governments developed a regional environmental management plan to control pollution in the bay. The plan was prepared through an extensive collaborative process that involved a broad spectrum of stakeholders—federal, state, and local regulatory agencies; business, labor, and environmental groups; ethnic minorities; and city and county governments. During the decision-making process, stakeholders raised important issues about federal-state-local relationships, the social and economic impact of land-use controls, and the extent of air-quality improvement likely to be obtained.

Stakeholders who were involved in analyzing problems and solutions and in making decisions supported the final plan and its implementation. And while some aspects of the plan might have been developed and implemented without the help of stakeholders, most of the actions were implemented more expeditiously as a direct result of stakeholder involvement.

Many actions recommended by the plan were implemented by public agencies, businesses, industries, and private citizens. For example:

- A state implementation plan for regional air quality resulted in designation under the federal Clean Air Act as an attainment area for ozone in 1995.
- Almost all the industrial and municipal wastewater treatment facilities have been upgraded.
- Erosion-control measures to reduce nonpoint-source pollution have been in place for many years.
- A council of water-supply agencies was formed and has engaged in cooperative efforts, such as developing a regional drought-response strategy.
- Hazardous-material spill response teams have become available at the city and county levels.
- Technical assistance was provided to local agencies to initiate recycling programs.



The plan has served as a blueprint for environmental management activities in the bay area.

BLANK PAGE

Evaluating Results

A good risk management decision can be shown to have a significant impact on the risks of concern.

Why Evaluate?

At this stage of risk management, decision-makers and other stakeholders review what risk management actions have been implemented and how effective they have been. Evaluating effectiveness involves monitoring and measuring, as well as comparing the actual benefits and costs to estimates made in the decision-making stage. The effectiveness of the process leading to implementation should also be evaluated at this stage.

Evaluation provides important information about:

- Whether the actions were successful, whether they accomplished what was intended, and whether the predicted benefits and costs were accurate.
- Whether any modifications are needed to the risk management plan to improve success.
- Whether any critical information gaps hindered success.
- Whether any new information has emerged that indicates a decision or a stage of the Framework should be revisited.
- Whether the Framework process was effective and how stakeholder involvement contributed to the outcome.

Monitoring health indices can be one method of evaluating whether risk management has been successful.

- What lessons can be learned to guide future risk management decisions or to improve the decision-making process.

Tools for evaluation include environmental and health monitoring, research, disease surveillance, analyses of costs and benefits, and discussions with stakeholders.

Evaluation is critical to accountability and to ensure wise use of scarce resources. Too often, past risk management actions have had little or no evaluation or follow-up after implementation, even when evaluation was mandated.

A good risk management decision can be revised and changed when significant new information becomes available, while avoiding "paralysis by analysis."

Planning for Evaluation

Plans for evaluation should be built into the overall implementation plan to specify when evaluation will be conducted, who will conduct it, and what will be evaluated. In most situations, periodic evaluation will be important. The focus of evaluation may shift with the stage of implementation, because it often may take some time before the full impact of risk reduction can be measured. Evaluation might first focus more on progress and success in implementing the risk management plan. Later evaluations may focus on the success of the risk management actions in reducing risk.

In the past, evaluation, when conducted, has been performed by the regulatory authority itself. As with

Evaluating Results: Integrating Regulatory Activities at the State Level

Environmental agencies in Massachusetts, New York, and New Jersey have made significant efforts to integrate their regulatory activities and to incorporate pollution prevention into these activities. Massachusetts has adopted a single, integrated inspection to assess a facility's compliance with environmental statutes, instead of conducting separate medium-specific inspections. New York is using a facility-management strategy in which a team directed by a state-employed facility manager is assigned to targeted plants to coordinate medium-specific environmental programs. New Jersey is testing the use of a single, integrated permit for industrial facilities instead of separate permits for releases of pollution to each environmental medium.

On behalf of Congress, the General Accounting Office (GAO) evaluated the states' experiences with integrated programs, primarily through interviews. The evaluation is considered preliminary because the data needed to fully evaluate the states' experiences are not yet available.

GAO reported that Massachusetts and New York believe that their integrated approaches have been sufficiently successful to implement them statewide. Permits have only recently been issued as part of New Jersey's program. Industry officials in those states believe that the integrated approaches are beneficial to the environment, achieve regulatory efficiencies, and reduce costs. However, the states noted that obtaining funding from EPA and meeting EPA's medium-specific reporting requirements were difficult and burdensome. In response, EPA proposed a new grant program designed to provide states with easier access to funding for multimedia programs and to facilitate easier reporting of multimedia activities. Such a program would encourage other states to integrate environmental management.

Measuring the Effectiveness of a Risk Management Action

Few actions to reduce health or ecosystem risks lend themselves easily to measurement and validation. For example, it is difficult to observe changes in cancer risk because it can take many years for a tumor to develop after exposure occurs. Some other effects are easier to observe because they can appear soon after exposure—such as birth defects, anemia from lead, and asthma from sulfur oxides in the air. Relationships between action and effect often are detectable only when the action causes a sizable change in how much of a pollutant (or other stressor) populations are exposed to, or when the health effect of interest is easy to recognize because it is rare and distinctive (such as the unusual type of liver tumor caused by breathing vinyl chloride in the workplace).

One difficulty in measuring effectiveness is that most environmental health risks are low compared with the risks of such directly countable effects as occupational injuries, motor-vehicle collisions, infant mortality, total cancer rates, and total birth defect rates. For example, suppose that a particular exposure is expected to cause no more than one additional case of cancer per year in a population of 10,000 and action is taken to reduce exposure to a level anticipated to cause, at most, one additional case of cancer per year in one million people (corresponding to one extra case per 100 years in that population of 10,000). With or without this action, cancer still will be the cause of death in 24% of the population. No health study or surveillance activity can measure the very small decrease in cancer incidence that would occur at the lower exposure level. Instead, risk managers must rely on indirect measures that indicate cancer incidence may decrease—such as decreased emissions, decreased exposure, and possibly decreases in biological markers of exposure or effects.

Progress is needed in several areas if we are to improve our ability to implement and measure the effectiveness of public health interventions. Specifically, we need to:

- Link studies of exposure and studies of adverse health or ecological outcomes.
- Determine regional differences in disease prevalence and disease incidence trends and risk factors.
- Develop good baseline and surveillance information about incidence rates of diseases specifically linked to environmental causes.
- Identify the most important environmental causes of diseases.

other stages of the risk management process, evaluation will benefit if stakeholders are involved, helping to:

- Establish criteria for evaluation, including the definition of "success."
- Assure the credibility of the evaluation and the evaluators.
- Determine whether an action was successful.
- Identify what lessons can be learned.
- Identify information gaps.
- Determine whether cost and benefit estimates made when evaluating the risk management options were reasonable.

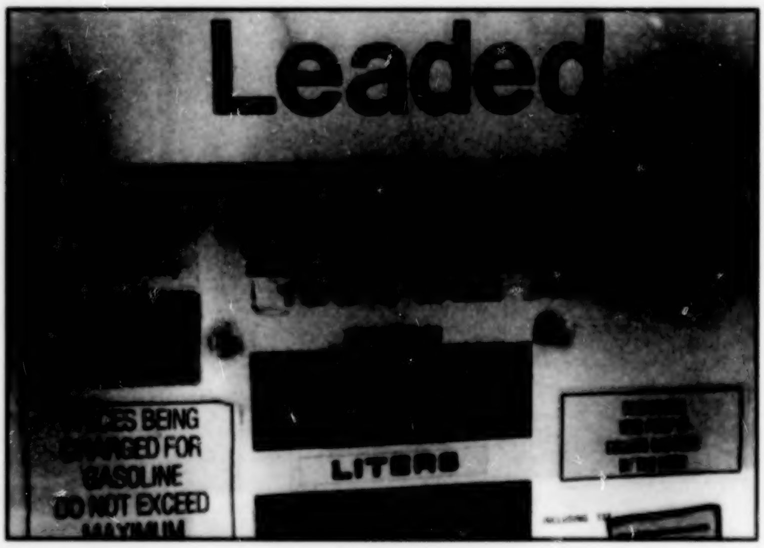
The Importance of Iteration

New information may emerge during evaluation that is of sufficient importance to indicate that parts of the Framework should be repeated. For example, revisiting a decision might be needed if a more effec-

tive risk management option or a less costly option of equal effectiveness is developed. Public comment, negotiation, information-gathering, research, or analysis of risks and options could clarify or redefine the problem, change the focus to a different problem, or identify other risks in a broader context. In such cases, the risk management process will not be sequential, but rather flexible and iterative as important new information, ideas, and perspectives come to light. The Commission's Risk Management Framework provides that flexibility.

While an iterative process is important for incorporating new information, it should not become an excuse for taking no action. Decisions must be made, even when information is imperfect.

Evaluating Results: Reducing the Use of Leaded Gasoline



One of best documented evaluations of the impact of a risk management action on pollutant emission levels concerns leaded gasoline. The burning of gasoline was the single largest source (90%) of lead in the atmosphere beginning in the 1920s. Significantly less of the lead monitored in the air today comes from gasoline because EPA phased out the use of lead in gasoline. In 1984, the average lead content of gasoline was 0.44 grams per gallon; in 1991-1992, it was less than 0.0003 grams per gallon. EPA estimated that before the regulations to control lead in gasoline were in place, the total amount of lead released to the air from motor vehicles was about 95 metric tons in 1979. After the controls were in place, only 2 metric tons were emitted from motor vehicles in 1989, with less than 35% of the lead in air attributable to gasoline. Today, the emission of lead from motor vehicles should be nearly zero, as required by the 1990 Clean Air Act.

Implementing the Framework

Recommendations to Congress and Executive Branch Agencies

Most environmental problems affect more than one environmental medium and involve exposures to mixtures of chemicals. The Commission's Risk Management Framework is designed to address these complex, real-world issues. Yet, environmental agencies may encounter legal and administrative hurdles when implementing the Framework because most environmental statutes, agency programs, and Congressional committees and subcommittees focus on managing individual pollutants in single environmental media. Current procedures also limit stakeholder involvement in decision-making and the ability of agencies to consider the larger context when addressing health and environmental problems. In short, the programs, regulations, and procedures developed under current statutes often preclude an integrated approach. The Commission makes six recommendations, described below, to overcome these impediments.

Recommendation 1: Congress should coordinate the activities of committees and subcommittees with overlapping or related jurisdictional responsibilities for environmental issues, starting with joint oversight hearings.

Many different Congressional committees and subcommittees have overlapping and conflicting responsibilities for sources of and solutions to pollution. For example, the Transportation and Infrastructure Committee and the Commerce Committee in the House of Representatives both oversee EPA's implementation of Superfund and the Safe Drinking Water Act. In the Senate, the Agriculture Committee has jurisdiction over pesticides, while the Environment and Public

FRIDAY, JUNE 14, 1996 **The New York Times**

New System of Assessing Health Risks Is Urged

By GINA KOLATA

In a draft report that is winning praise from environmentalists and the chemical industry, a Federal commission recommended yesterday that the system of assessing and regulating health hazards from environmental pollutants and other sources, like food additives, be overhauled.

The 10-member Commission on

"we have a Clean Water Act that regulates a whole list of chemicals in the water, but we don't ask about exposures" to that chemical from other sources.

From the very beginning, risk assessments should include all interested parties, from citizens to those who work with or near the chemicals to environmentalists to industry, the commission said.

praised the report as "a significant contribution and a major advance," but Mr. Roe said he wished the group had addressed the question of incentives. For example, he said, how can industry be coaxed to provide the information on chemicals that is needed for risk assessment?

"A constant theme is that there is a body of information we need to know but don't know," he said. "We

As this recent article from *The New York Times* shows, the public is keenly aware of the need for improved approaches to controlling health risks.

Works Committee oversees other toxic substances. These competing responsibilities make it difficult to implement integrated strategies. We recognize the practical and political constraints that make coordination difficult.

Joint Congressional hearings could:

- Help put problems into public health or ecological context.
- Encourage EPA and other agencies to use their discretionary authority to implement the Commission's Risk Management Framework and comprehensive risk assessment reforms.
- Reinforce integrated approaches to reducing risks in industrial sectors and geographic areas.
- Evaluate experimental alternatives to command-and-control regulations.

For example, the Agriculture Committee and the Resources Committee in the House could stimulate coordinated approaches to integrating chemical and microbial risk assessment and benefit-cost practices throughout the U.S. Department of Agriculture. They could also promote the use of the Commission's Risk Management Framework by the Natural Resources Conservation Service in addressing erosion and water pollution from agricultural lands. Other committees should look at industrial sectors, such as iron and steel mills or oil refineries, to address sector-specific pollution and manufacturing processes on a multimedia basis.

Some committees address the environmental status of geographic areas, such as the House Resources Committee's jurisdiction over parks, wild and scenic rivers, and national forests, but no committee is charged with responsibility for the status of urban pollution or of watersheds. In the House, joint hearings involving the Resources Committee, the Agriculture Committee, and the Transportation and Infrastructure Committee, which has jurisdiction over the Clean Water Act, could better address the myriad stresses on a watershed. Similarly, the House Commerce Committee and the Transportation and Infrastructure Committee could hold joint hearings to encourage the use of the Commission's Risk Management Framework to comprehensively deal with Superfund sites.

Recommendation 2: The regulatory agencies should fully use their existing discretionary authority to propose and implement actions that address the most significant sources of total exposure to hazards under review.

Many agencies have improved their risk assessment practices, used risk assessment in more programs, and begun to engage stakeholders in decision-making processes. In many cases, adoption of the Commission's Risk Management Framework by federal, state, and local agencies will not require changes in statutes so much as changes in the decision-making process to identify all the sources that account for total exposure and estimate the risks attributable to each source.

California's air toxics program provides a good model of an integrated regulatory strategy that is being achieved administratively. Rather than first assessing risks from individual sources, that program estimates the overall risk attributable to a particular chemical. Upon deciding that the risk is sufficiently high to warrant action, the program examines all identified stationary, mobile, and area sources of the chemicals to determine the most cost-effective reductions in emissions and exposure. The EPA has launched a similar cumulative exposure approach for hazardous air pollutants (see below).

> "As a Commissioner, I saw far too many cases where extreme attention was placed at an industrial facility on ensuring that every last molecule of a toxic substance was kept out of the air, only to have that same substance ignored as it poured through the floor drain into the groundwater . . . . Taking a look at whole facilities, at the whole mix of pollutants, at whole watersheds, is fundamental."
>
> —Daniel Greenbaum,
> President of the Health Effects Institute
> Former Commissioner for
> Environmental Protection, State of Massachusetts

Recommendation 3: The regulatory agencies should fully use their existing discretionary authority to expand stakeholder involvement in the development and implementation of solutions to environmental problems.

Successful integrated approaches depend on trust among agencies and stakeholders. Public notice and comment procedures are inadequate for building the level of trust and cooperation necessary for integrated approaches. Stakeholder involvement processes such as those used in the Common Sense Initiative and Project XL are a good beginning. As the participants have learned, however, unexpected difficulties—such as disagreements about the composition of stakeholder groups and problems arriving at consensus—have slowed the completion of projects. We believe that implementation of our "Guidelines for Stakeholder Involvement" (see page 16) can increase prospects for productive stakeholder involvement. Agency adoption of the Commission's Framework for Risk Management can provide a consistent approach to risk management decision-making.

Recommendation 4: Congress should reinforce implementation of the Commission's Risk Management Framework legislatively, statute-by-statute.

For several years, Congress has considered bills that would prescribe government-wide risk assessment and economic analysis practices and make them judicially enforceable. Also, an "organic act" has been proposed that would integrate the operations of EPA's program offices. However, the 104th Congress found, common ground for bipartisan action by reauthorizing specific statutes instead. For example, the Safe Drinking Water Act and the Food Quality Protection Act were modified in ways that provide flexible direction to consider risks, costs, benefits, population subgroups, and public values in decision-making. The 1996 Safe Drinking Water Act includes important provisions on the roles of risk assessment and economic analysis in setting standards and priorities for regulation without dictating the specific steps in the analysis or requiring one to outweigh another. It is a good example of how statutes can be modified to promote more flexible risk management strategies. Congress should consider legislative changes that:

- *Address geographic areas such as urban areas and watersheds.* Under the Clean Air Act Amendments of 1990, EPA is developing an integrated urban air toxics strategy that considers different types of pollutants and multiple sources of pollutants together, so that risk management actions in urban areas can address air pollution in context. In the case of watersheds, EPA already is working with states and localities to develop ecological risk assessments and integrated approaches to pollution problems. The Clean Water Act should be amended to establish a comprehensive, integrated watershed management approach.

- *Mandate authority for EPA to consider sources of significant indoor air pollution when evaluating the risks attributable to multiple sources of air pollution. EPA should collaborate with other agencies to reduce significant risk*

from indoor air exposures. Numerous studies have shown that the concentrations of many contaminants in air are higher in homes than outdoors. While outdoor air pollution is extensively regulated, problems in offices, public buildings, and homes remain relatively unrecognized and unaddressed. Efforts by the EPA, Consumer Product Safety Commission (CPSC), and Occupational Safety and Health Administration (OSHA) to regulate indoor air have been thwarted by lack of statutory authority and by lack of agreement on the nature of the problems and the solutions. EPA's regulatory authority appears to be limited to outdoor air. OSHA is responsible for industrial environments. CPSC has authority over products, such as carpets and insulating materials. A coordinated approach by EPA, OSHA, and CPSC will not emerge without a mandate from Congress and cooperation from stakeholders.

- *Increase flexibility for meeting environmental protection goals.* Integrated approaches to compliance can provide greater cost-effectiveness and increased flexibility for facilities that go beyond current levels of environmental protection. EPA is currently experimenting with such approaches in its Common Sense Initiative and Project XL programs. However, EPA and participants must still meet the original regulatory requirements, even when more effective solutions are being implemented. For these projects to succeed, EPA needs the legal authority to provide flexibility in deciding how the regulated community can improve its environmental performance. Congress should explicitly authorize EPA and state agencies to enter into compliance agreements that waive certain current regulatory requirements if alternative controls can credibly achieve equal or, whenever feasible, greater environmental protection.

Recommendation 5: The Council on Environmental Quality (CEQ) should consider issuing guidance or regulations for implementing additional provisions of the existing National Environmental Policy Act (NEPA).

The National Environmental Policy Act offers some opportunities for implementing the Framework. Instead of aiming to protect specific places, activities, or environmental media, as do most environmental statutes, NEPA seeks to balance a broad range of environmental factors with "other essential considerations of national policy." The act states that its policies and goals are supplementary to those in agencies' existing statutory authorizations. NEPA regulations, which were issued in 1978, focused on procedural provisions to ensure that decisions about federal actions are made only after the environmental consequences of the actions are fully considered and that the public benefits of the actions outweigh their environmental costs. These regulations are generally consistent with the focus of the Framework.

In addition to procedural requirements, NEPA established six objectives for all federal programs: responsibility for the future; environmental equity; beneficial use; historical, cultural, and biological diversity and individual liberty; widespread prosperity; and management for quality and conservation. The act requires all federal agencies to use a "systematic, interdisciplinary approach" to planning and decision-making that incorporates the "natural and social sciences and the environmental design arts." An analysis by the Environmental Law Institute concluded that these provisions have not been implemented. Agencies could use these objectives to approach problems in the integrated, contextual manner envisioned in the Commission's Risk Management Framework. CEQ should work with other executive offices and the relevant federal agencies to craft guidance for implementing these NEPA provisions.

Recommendation 6: State and local regulatory and public health agencies should use the Risk Management Framework, as many already do to some extent, to address watershed, airshed, community, worksite, and indoor and outdoor environmental problems using an integrated, multimedia process with stakeholders.

We have given several examples of state and local actions that have been taken to address problems in a broad context with stakeholder involvement, such as California's toxics air program and efforts in Massachusetts, New York, and New Jersey to integrate regulatory actions. As in other areas of government endeavor, states and localites engaged in successful integrated risk management projects can serve as catalysts for federal initiatives. However, state and local agencies often rely on federal models of regulation. As a result, they, too, focus primarily on single pollutants in single environmental media and on command-and-control approaches to regulation. State and local agencies should increase their ability both administratively and legislatively to implement the Commission's Risk Management Framework.

Looking Ahead

The Commission's Risk Management Framework is not a panacea. It can require substantial time to implement and, in some cases, it might lengthen, not shorten, the risk management process. The ability to implement the Framework will undoubtedly improve over time as more experience is gained with its various aspects and as more relevant information becomes available. For example, more experience with and guidance for including stakeholders is needed. Both agencies and stakeholders need training to better understand and discuss health and environmental risk issues. Agencies and academic institutions must cooperate to generate more and better exposure and toxicity data and methods for assessing multiple and cumulative risks.

As illustrated in this report, some aspects of the Framework—such as stakeholder involvement and multimedia analysis—already are in use to some extent. However, no risk management effort to date has employed all aspects of the Framework. Many of the questions and concerns associated with implementing the Framework will be clarified as it is applied and evaluated. However, gaining experience with the Framework can best be achieved if Congress and the Administration work together to overcome the statutory and administrative barriers described above.

In using this Framework, risk scientists and decision-makers will be embarking on an important new era in risk management designed to make wise use of limited risk management resources. As described throughout this report, the Framework's advantages include:

- Use of an integrated, holistic approach to make risk management more efficient and effective compared with the traditional chemical-by-chemical, medium-by-medium approach to characterizing individual risks.
- Identification and targeting of the most important sources of risk by putting individual problems into larger public health and environmental contexts and addressing multiple and cumulative risks.
- Emphasis on collaboration, communication, and negotiation in an open and inclusive process among stakeholders so that public values can inform and influence the shaping of risk management strategies. Stakeholder involvement can help generate decisions that are more pragmatic and more readily implemented than decisions that are made without considering the diversity of interests, knowledge, and technical expertise represented among stakeholders.

- Capacity for iteration. As with the scientific process itself, at any stage of the Framework, the discovery of critical new information can change conclusions and decisions and lead to reformulation and reevaluation of the problem at hand.

The Commission envisions the Framework to be far more useful and effective than traditional regulatory approaches to solving common multimedia risk problems.

Resources

The following reports and organizations can provide additional information on the conduct and application of risk assessment, risk management, and risk-based decision-making.

Reports

Albert, R.E. 1994. Carcinogen risk assessment in the U.S. Environmental Protection Agency. Critical Reviews in Toxicology 24:74-85

American Industrial Health Council (AIHC). 1993. Ecological Risk Assessment: Sound Science Makes Good Business Sense. Washington, DC

Arrow, K.J., Cropper, M.L., Eads, G.C., Hahn, R.W., Lave, L.B., Noll, R.G., Portney, P.R., Russell, M., Schmalensee, R., Smith, V.K., and Stavins, R.N. 1996. Benefit-Cost Analysis in Environmental, Health, and Safety Regulation. A Statement of Principles. Sponsored by the Annapolis Center, the American Enterprise Institute, and Resources for the Future. Washington, DC

Association of Bay Area Governments (ABAG). 1978. Environmental Management Plan for the San Francisco Bay Area. Berkeley, CA

Burke, T.A., Shalauta, N.M., and Tran, N.L. 1995. Strengthening the role of public health in environmental policy. Policy Studies Journal 23:76-84

Carnegie Commission on Science, Technology, and Government. 1993. Risk and the Environment. Improving Regulatory Decision-Making. New York, NY

Chess, C., Salomone, K.L., Hance, B.J., and Saville, A. 1995. Results of a national symposium on risk communication: Next steps for government agencies. Risk Analysis 15:115-125

Council for Excellence in Government. 1996. National Public Opinion Survey. Prepared by Peter Hart and Robert Teeter, Inc. Washington, DC

Faustman, E.M. and Omenn, G.S. 1995. Risk Assessment. Chapter 4. In: C.D. Klaassen, ed. Casarett and Doull's Toxicology. The Basic Science of Poisons. Fifth Edition. McGraw-Hill: New York, pp. 75-88

Goldman, L.R. 1995. Environmental risk assessment and national policy: Keeping the process fair, effective, and affordable. University of Cincinnati Law Review 63:1533-1551

Health Effects Institute (HEI). 1996. The Potential Health Effects of Oxygenates Added to Gasoline: A Review of the Current Literature. A Special Report. Cambridge, MA

Goldstein, B.D. 1996. Risk assessment as an indicator for decision making. In: Risks, Costs, and Lives Saved: Getting Better Results from Regulation, ed. Oxford University Press. New York, NY

Ikeda, M. 1988. Multiple exposure to chemicals. Regulatory Toxicolology and Pharmacology 8:414-421

Jasanoff, S. 1996. The dilemma of environmental democracy. Issues in Science and Technology. Fall:63-70

Lave, L.B., Ennever, F.K., Rosenkranz, H.S., and Omenn, G.S. 1988. Information value of the rodent bioassay. Nature 336:631-633

McGinnis, J.M. and Foege, W.H. 1993. Actual causes of death in the United States. Journal of the American Medical Association 270:2207-2212

Morgan, M.G., Fischoff, B., Bostrom, A., Lave, L., and Atman, C.J. 1992. Communicating risk to the public. Environmental Science and Technology 26:2048-2056

National Academy of Public Administration (NAPA). 1995. Setting Priorities, Getting Results: A New Direction for EPA. Washington, DC

National Commission on the Environment. 1992. Choosing a Sustainable Future. World Wildlife Federation. Washington, DC

National Research Council (NRC). 1983. Risk Assessment in the Federal Government: Managing the Process. National Academy Press. Washington, DC

Resources

National Research Council (NRC). 1988. Complex Mixtures. National Academy Press. Washington, DC

National Research Council (NRC). 1989. Improving Risk Communication. National Academy Press. Washington, DC

National Research Council (NRC). 1993. Pesticides in the Diets of Infants and Children. National Academy Press. Washington, DC

National Research Council (NRC). 1994. Building Consensus Through Risk Assessment. National Academy Press. Washington, DC

National Research Council (NRC). 1994. Science and Judgment in Risk Assessment. National Academy Press. Washington, DC

National Research Council (NRC). 1996. Understanding Risk. Informing Decisions in a Democratic Society. National Academy Press. Washington, DC

North, D.W., Selker, F.K., and Guardino, T. 1992. Estimating the Value of Research: An Illustrative Calculation for Ingested Inorganic Arsenic. Decision Focus Inc. Report. Mountain View, CA

Office of Technology Assessment (OTA). 1995. Gauging Control Technology and Regulatory Impact in Occupational Safety and Health—An Appraisal of OSHA's Analytic Approach. OTA-ENV635. Washington, DC

Omenn, G.S. 1996. Putting environmental risks in a public health context. Public Health Reports 111:514-516

Omenn, G.S. and Faustman, E. 1997. Risk assessment, risk communication, and risk management. In: R. Detels, W. Holland, J. McEwen, and G.S. Omenn, eds. Oxford Textbook of Public Health. Third Edition. Oxford University Press. Oxford, UK, pp. 969-986

Organization for Economic Cooperation and Development (OECD). 1996. Environmental Performance Reviews: United States. Paris, France

President's Council on Sustainable Development (PCSD). 1996. Sustainable America. A New Consensus for Prosperity, Opportunity, and a Healthy Environment for the Future. Washington, DC

Richards, M. 1993. Siting Industrial Facilities. Lessons from the Social Science Literature. Presented at the Fifth Annual International Conference of the Society for the Advancement of Socio-Economics. Environmental Decision-Making. New York City. March 26-28

Ruckelshaus, W.D. 1995. Stopping the pendulum. The Environmental Forum. Nov./Dec., pp. 25-29

Slovic, P. 1987. Perception of risk. Science 236:280-285

U.S. Department of Energy (DOE). 1995. Risks and the Risk Debate: Searching for Common Ground. Office of Environmental Management. Washington, DC

U.S. Environmental Protection Agency (EPA). 1987. The Total Exposure Assessment Methodology (TEAM) Study. Summary and Analysis. EPA/600/6-87/002a. Office of Acid Deposition, Environmental Monitoring and Quality Assurance. Washington, DC

U.S. Environmental Protection Agency (EPA). 1987. Unfinished Business: A Comparative Assessment of Environmental Problems. Office of Policy Analysis. Washington, DC

U.S. Environmental Protection Agency (EPA). 1990. Reducing Risk: Setting Priorities and Strategies for Environmental Protection. Science Advisory Board. SAB-EC-90-0021. Washington, DC

U.S. Environmental Protection Agency (EPA). 1992. Guidelines for Exposure Assessment. Federal Register 57(May 29):22888-22938

U.S. Environmental Protection Agency (EPA). 1992. Framework for Ecological Risk Assessment. EPA/630/R-92/001. Risk Assessment Forum. Washington, DC

U.S. Environmental Protection Agency (EPA). 1992. Safeguarding the Future: Credible Science, Credible Decisions. Report of the Expert Panel on the Role of Science at EPA. EPA/600/9-91/050. Washington, DC

U.S. Environmental Protection Agency (EPA). 1993. Motor Vehicle-Related Air Toxics Study. Ann Arbor, MI

U.S. Environmental Protection Agency (EPA). 1993. A Review of Ecological Assessment Case Studies from a Risk Assessment Perspective. Risk Assessment Forum. EPA630-R-92-005. Washington, DC

U.S. Environmental Protection Agency (EPA). 1995. Guidance for Risk Characterization. Science Policy Council. Washington, DC

U.S. Environmental Protection Agency (EPA). 1996. Proposed Guidelines for Carcinogen Risk Assessment. EPA/600/P-92/003C. Office of Research and Development. Washington, DC

U.S. General Accounting Office (GAO). 1996. Peer Review. EPA's Implementation Remains Uneven. GAO/RCED-96-236. Resources, Community, and Economic Development Division. Washington, DC

Organizations

U.S. EPA Center for Environmental Research Information (CERI) Publications
26 West Martin Luther King Drive
Cincinnati, OH 45268
Phone Number: 513-569-7562

• Distributes brochures, reports, handbooks, newsletters, and manuals based on the scientific and technical environmental information produced by EPA.

U.S. EPA Public Information Center (PIC)
401 M Street, SW
Washington, DC 20460
Phone Number: 202-260-2080 or 202-260-7751

• Distributes a wide variety of general, nontechnical information about EPA and its programs.

USDA-ARS-HRS/MOB
Agriculture Resource Service
Human Resource Division
1400 Independence Avenue, SW
Stop 0308
Washington, DC 20250-0308
Phone Number: 202-720-6539
(or see your local directory for your local or county extension agent)

• Provides education in wastewater and other environmental subjects for local officials and residents.

International City/County Management Association
777 North Capitol Street, NE, Suite 500
Washington, DC 20002
Phone Number: 202-289-4262

• Provides information and training for local governments on a variety of issues. Sets up peer matches for people to learn from one another.

Northeast Center for Comparative Risk
Vermont Law School
P.O. Box 96
Chelsea Street
South Royalton, VT 05068
Phone Number: 802-763-8303
or
Western Center for Comparative Risk
5398 Manhattan Circle
Boulder, CO 80303
Phone Number: 303-494-6393

• Both work with EPA to help states and cities use comparative risk analysis. Can provide small communities with publications on comparing environmental risks.

National Association of Towns and Townships
1522 K Street, NW
Washington, DC 20005
Phone Number: 202-624-3550

• Offers educational services, technical assistance programs, and public policy support to local governments.

National Environmental Training Center
West Virginia University
P.O. Box 6064
Morgantown, WV 26506
Phone Number: 800-624-8301

• Develops training materials on water, wastewater, and solid waste issues.

Small Towns Environment Program
The Rensselaerville Institute
Rensselaerville, NY 12147
Phone Number: 518-797-3783

• Helps small towns solve water and wastewater problems. Provides tools for local action, self-help approaches to design and construction, nonbureaucratic low-interest loans, and technical support.

Solid Waste Association of North America
P.O. Box 7219
Silver Spring, MD 20907
Phone Number: 301-585-2898

• Works to improve solid waste management services to the public and industry via training, education, technical assistance, and technology transfer. Also maintains information on local government issues as they relate to solid and hazardous waste management.

Control Technology Center (CTC) Hotline
Phone Number: 919-541-0800

• Provides technical support and information on air pollution emissions and control technology.

Emissions Measurement Technical Information Center
Phone Number: 919-541-1060

• Provides information on air emissions testing methods and federal testing and monitoring requirements.

Resources

Air Risk Hotline
Phone Number: 919-541-0888

• Provides information on aspects of air risk.

National Response Center
Phone Number: 800-424-8802

• Receives notification of oil, hazardous chemical, biological, and radiological releases, and passes them on to a federal on-scene coordinator, who coordinates cleanup efforts.

Resource Conservation and Recovery Act (RCRA)/ Superfund/Emergency Planning and Community Right-to-Know Act (EPCRA) Hotline
Phone Number: 800-424-9346 or 800-535-0202 or 703-412-9810

• Provides general assistance and information on solid and hazardous waste management and on EPCRA.

Pollution Prevention Information Clearinghouse
Phone Number: 202-260-1023

• Provides technical, policy, programmatic, legislative, and financial information about reducing industrial pollutants.

Clean Lakes Clearinghouse
Phone Number: 800-726-5253

• Provides information on lake and watershed restoration, protection, and management.

Safe Drinking Water Hotline
Phone Number: 800-426-4791

• Assists public water systems and the public with their understanding of the regulations and programs developed in response to the Safe Drinking Water Act Amendments of 1986 (and is presumably updating information for the reauthorized act).

Wetlands Information Hotline
Phone Number: 800-832-7828

• Responds to requests for information about the value and functions of wetlands and options for their protection.

Inform, Inc.
120 Wall Street
New York, NY 10005
Phone Number: 212-361-2400

• Provides reports on practical solutions for problems in municipal solid waste, chemical hazards, air quality, and alternative vehicle fuels.

Glossary

affected parties — Individuals and organizations acted upon by chemicals, radiation, or microbes in the environment or influenced favorably or adversely by proposed risk management actions and decisions.

alternative compliance — A policy which allows facilities to choose among methods for achieving emission-reduction or risk-reduction specifications instead of command-and-control regulations that specify standards and how to meet them. An example of alternative compliance is the use of a theoretical bubble over a facility to cap the amount of pollution emitted while allowing the company to choose where and how within the facility it gets to or stays below the cap.

attainment area — A geographical area, such as a city, state, or regional airshed, that is meeting EPA clean air standards.

benefit-cost analysis (BCA) — An economic method for assessing the benefits and costs of achieving alternative health-based standards with different levels of health protection.

collaborative stakeholder involvement — Engaging interested and affected parties in the substantive work of risk management, through all 6 stages of the Commission's Framework.

command-and-control regulations — Specific requirements prescribing how to comply with specific standards defining acceptable levels of pollution.

Common Sense Initiative — A current EPA initiative that convenes teams of stakeholders in six major industrial sectors— automobile manufacturing, computers and electronics, iron and steel, metal finishing, petroleum refining, and printing—to find comprehensive and feasible strategies to reduce pollution.

contaminants — Chemicals, microorganisms, or radiation found in air, soil, water, or food that are not normally constituents of these environmental media.

context — Here refers to public health and ecological assessment of the contribution of any particular environmental hazard to health, safety, or the environment.

cost-effectiveness analysis (CEA) — An economic method to identify the least costly way to achieve a particular health protection goal.

cumulative — Enlarging or increasing by successive addition.

disease incidence — The rate of new occurrences of a disease.

exposure-response relationship — The relationship between exposure level and the incidence of adverse effects.

ecological risk assessment — A process used to estimate the likelihood of adverse effects on plants or animals from exposure to stressors, such as chemicals or the draining of wetlands. The process includes problem formulation, characterization of exposure, characterization of ecological effects, and risk characterization.

economic analysis — An analysis in monetary values of the costs and benefits of various actions to protect health or the environment.

Glossary

end of the pipe	Relying on technologies, such as scrubbers on smokestacks and catalytic converters on vehicle tailpipes, to reduce emissions of pollutants after they have formed.
environmental justice	Concern about the disproportionate occurrence of pollution and potential pollution-related health effects affecting low-income, cultural, and ethnic populations and lesser cleanup efforts in their communities.
epidemiology	The core public health science, investigating the causes and risk factors of disease and injury in populations and the potential to reduce such disease burdens.
equity	Just, fair, and impartial treatment of all people and population groups, including low-income, cultural, and ethnic populations potentially more affected by pollution.
exposure assessment	Determination of the sources, environmental transport and modification, and fate of pollutants and contaminants including the conditions under which people or other target species, could be exposed and the doses that could result in adverse effects.
exposure pathway	The path from sources of pollutants via air, soil, water, or food to reach people and other potentially affected species or settings.
hazard	A source of possible damage or injury.
interdependence	Mutual dependence.
iterative process	Replication of a series of actions to produce successively better results, or to accommodate new and different critical information or scientific inferences.
life cycle	Tracking a product through all stages of its development, from extraction of fuel for power to production, use, and disposal.
maximum available control technology (MACT)	The emission standard for sources of air pollution requiring the maximum reduction of hazardous air pollutant emisssions, taking cost and feasibility into account. Under section 112 of the Clean Air Act Amendments of 1990, the MACT must not be less than the average emission level achieved by controls on the best performing 12% of existing sources, by category of industrial and utility sources.
multimedia approach	A process for considering several environmental media, such as air, water, and land, together, rather than in isolation.
multiple risks	Risks from several sources or many agents.
options	Choices of actions.
peer review	Evaluation of the accuracy or validity of technical data, observations, and interpretation by qualified experts in an organized group process.
precautionary principle	Decisions about the best ways to manage or reduce risks that reflect a preference for avoiding unnecessary health risks instead of unnecessary economic expenditures when information about potential risks is incomplete.

Project XL .... An EPA initiative to give (as of 1996) six companies (Intel, Anheuser Busch, HADCO, Merck, AT&T Microelectronics, and 3M) and two government agencies (California's South Coast Air Quality Management District and the Minnesota Pollution Control Agency) the flexibility to develop comprehensive strategies as alternatives to multiple current regulatory requirements to exceed compliance and increase overall environmental benefits.

public health context .... The incidence, prevalence, and severity of diseases in communities and populations and the factors that account for such problems that can be reduced or prevented, including smoking, alcohol consumption, poor diet, motor vehicle accidents, infections, chemical exposures, and other common voluntary and involuntary exposures or activities.

public health approach .... Focuses on effective and feasible risk management actions at the community level to reduce exposures and risks, with priority given to reducing exposures with the biggest impacts in terms of the number of people affected and severity of effect.

residual risk .... The health risk remaining after risk reduction actions are implemented, such as risks associated with sources of air pollution that remain after the implementation of maximum achievable control technology.

risk .... The probability of a specific outcome, generally adverse, given a particular set of conditions.

risk assessment .... An organized process used to describe and estimate the likelihood of adverse health outcomes from environmental exposures to chemicals. The four steps are hazard identification, dose-response assessment, exposure assessment, and risk characterization.

risk characterization .... The process of organizing, evaluating, and communicating information about the nature, strength of evidence, and likelihood of adverse health or ecological effects from particular exposures.

risk management .... The process of analyzing, selecting, implementing, and evaluating actions to reduce risk.

screening risk assessment .... A risk assessment performed using few data and many assumptions to identify exposures that should be evaluated more carefully for their potential risks.

toxicity .... The adverse effects of chemicals on living organisms.

value of information .... Value-of-information techniques provide an analytic framework for deciding whether it is better to make a decision now based on an inherently uncertain risk assessment as to collect additional information first and then decide.

weight of the scientific evidence .... Considerations involved in assessing the interpretation of published information about toxicity—quality of testing methods, size and power of the study design, consistency of results across studies, and biological plausibility of exposure-response relationships and statistical associations.

Appendix
Table of Contents for Volume 2 of the Commission's Final Report

Contents of Volume 2

END

06/17/98